

US3592061 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:18:28

All time stamps listed in this document are displayed in GMT

US3592061

Form: Participant Creation

Data signed: (b) (4) 25 Mar 2021 20:10:22

Generated On: 10 Jun 2021 08:18:28

[Participant ID](#)

US3592061

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

US3592061

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Date of Informed Consent (dd MMM yyyy) 8 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	MYOPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	BILATERAL ASTIGMATISM
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JAN 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 08:52
Height (xxx.x)	170.0 cm
Weight (xxx.x)	105.8 kg
BMI (xxx.x)	36.60900 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Date of assessment (dd MMM yyyy) 8 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) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 102295

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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)	8 AUG 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 08:52
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 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)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 AUG 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 10:11
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 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) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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) 8 AUG 2020

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 09:42

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) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 AUG 2020
Collection time (00:00-23:59)	09:10 (24 HR)
Collection date and time (derived)	8 AUG 2020 09:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:14	8 AUG 2020 09:14
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 10:20

PC Open Date & Time

08 AUG 2020 10:02

PC Close Date & Time

08 AUG 2020 12:32

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

08 AUG 2020 21:14

PC Open Date & Time

08 AUG 2020 13:27

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 22:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 22:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 22:16

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 00:51

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 AUG 2020 21:42

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 00:28

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 10:22

PC Open Date & Time

08 AUG 2020 10:02

PC Close Date & Time

08 AUG 2020 12:32

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

08 AUG 2020 21:15

PC Open Date & Time

08 AUG 2020 13:27

PC Close Date & Time

09 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

09 AUG 2020 22:27

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

10 AUG 2020 22:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

11 AUG 2020 22:17

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

13 AUG 2020 00:51

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

13 AUG 2020 21:42

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

15 AUG 2020 00:28

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 10:21
PC Open Date & Time	08 AUG 2020 10:02
PC Close Date & Time	08 AUG 2020 12:32

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 21:15
PC Open Date & Time	08 AUG 2020 13:27
PC Close Date & Time	09 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2772

EAB) (1725)

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 22:28
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

55 of 2772

EAB) (1725)

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:12
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 2772

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:17
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

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)

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 00:51
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

61 of 2772

EAB) (1725)

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:43
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2772

EAB) (1725)

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 00:29
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 16 AUG 2020 00:00

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 17 AUG 2020 05:39

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 16 AUG 2020 00:00

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 AUG 2020 00:00
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3592061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:18:22

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:18:22

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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)	5 SEP 2020
Time of assessment (00:00-23:59)	07:54 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 07:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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)	5 SEP 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 09:23
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	5 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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) 5 SEP 2020

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 5 SEP 2020 08:51

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

US3592061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 SEP 2020
Collection time (00:00-23:59)	08:14 (24 HR)
Collection date and time (derived)	5 SEP 2020 08:14

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)			5 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	5 SEP 2020 08:15
Nasopharyngeal Swab 2	No		

US3592061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 09:27

PC Open Date & Time

05 SEP 2020 09:11

PC Close Date & Time

05 SEP 2020 11:41

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	06 SEP 2020 08:08
PC Open Date & Time	05 SEP 2020 12:36
PC Close Date & Time	06 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 SEP 2020 06:49

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:08

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

98.5 °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

10 SEP 2020 20:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 09:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 09:28

PC Open Date & Time

05 SEP 2020 09:11

PC Close Date & Time

05 SEP 2020 11:41

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 08:08

PC Open Date & Time

05 SEP 2020 12:36

PC Close Date & Time

06 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 06:49

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

08 SEP 2020 22:09

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

09 SEP 2020 20:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

10 SEP 2020 20:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 09:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 09:28
PC Open Date & Time	05 SEP 2020 09:11
PC Close Date & Time	05 SEP 2020 11:41

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

No ☒

Yes ☐

PC Time stamp	06 SEP 2020 08:08
PC Open Date & Time	05 SEP 2020 12:36
PC Close Date & Time	06 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 06:50
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:09
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

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)

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:30
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:50
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

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 ☒

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EAB) (1725)

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 09:01
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3592061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:18:22

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:18:22

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:48:05

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:48:05

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:47

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	14:38 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 14:38
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

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.

US3592061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	14:57 (24 HR)
Collection date and time (derived)	5 OCT 2020 14:57

US3592061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:03:48

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 08:28:27
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 OCT 2020 11:18:23
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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	23 OCT 2020 20:11:13
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 06:47:16
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 NOV 2020 10:23:42
Patient Cloud Open Date & Time	12 NOV 2020 00:01
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 NOV 2020 02:15:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 NOV 2020 22:59:07
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 06:58:44
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

09 DEC 2020 10:33:51

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

14 DEC 2020 00:01:27

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

21 DEC 2020 04:08:00

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

28 DEC 2020 20:49:02

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

04 JAN 2021 02:17:40

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 06:05:39
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 JAN 2021 05:15:19
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

28 JAN 2021 13:36:22

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 09:10:27

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 08:13:51
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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	15 FEB 2021 06:57:50
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

24 FEB 2021 06:58:29

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 <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	01 MAR 2021 08:42:48
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 11:38:21

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 09:10:34

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 06:52:26

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 MAR 2021 10:24:17
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 07:58:21
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

13 APR 2021 10:18:15

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 10:06:41

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 07:27:23
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 07:05:14

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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18 FEB 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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04 MAR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 <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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 <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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3592061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:18:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:43:01

US3592061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:43:18

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:43:18

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

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) _____

US3592061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

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.

US3592061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 MAR 2021

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

8 MAR 2021 14:30

US3592061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 25 Mar 2021 20:10:23

Generated On: 10 Jun 2021 08:18:28

Date of Contact	13 NOV 2020
Time of Contact	11:07
Date and Time of Contact (derived)	13 NOV 2020 11:07
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	11 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	12 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	13 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	36.6 C
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	14 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	97.1 F
-------------	--------

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

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

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

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

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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	15 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	16 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	17 NOV 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

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Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	18 NOV 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Symptom Day

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Date	19 NOV 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 25 Mar 2021 20:10:23

Generated On: 10 Jun 2021 08:18:28

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	Yes	17 NOV 2020
Day 7	No	19 NOV 2020
Day 9	Yes	21 NOV 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3592061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 15:10
Height (xxx.x)	170.0 cm
Weight (xxx.x)	108.8 kg
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592061

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3592061

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3592061

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

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3592061

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3592061

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Height	
Weight	107.6 kg
BMI (xxx.x)	

US3592061

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Height	
Weight	107.6 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:34
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Height	
Weight	107.6 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:42
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

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

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3592061

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

Form: Pregnancy Test

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	12 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3592061

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

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 14:09 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 14:09

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

US3592061

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	13:43 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:43

US3592061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	13:40
Collection Date and Time (derived)	12 JAN 2021 13:40

US3592061

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

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag 1

OLD29 Placebo Flag 1

US3592061

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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)	10 FEB 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:25
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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)	10 FEB 2021
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 11:32
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3592061

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	10 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3592061

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 10 FEB 2021

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

Treatment Date and Time (derived) 10 FEB 2021 11:00

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: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 20:10:25

Generated On: 10 Jun 2021 08:18:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 MAR 2021
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 14:11
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

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.

US3592061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 20:10:24

Generated On: 10 Jun 2021 08:18:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 MAR 2021

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

8 MAR 2021 14:30

US3592061

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

AEID	USA-US103-2021-MRNA-1273-P30 1000007
Adverse event	SUICIDAL IDEATIONS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	28 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

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	False
Concomitant Medication	True
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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SUBJECT RESPONDED TO WEEKLY DIARY PROMPT INDICATION HAVING HAD CONTACT WITH A HEALTHCARE PROVIDER SINCE LAST CONTACT WITH SITE. RESEARCH ASSISTANT CALLED SUBJECT TO OBTAIN DETAILS AT WHICH TIME SUBJECT REPORTED THAT SHE VISIT THE ER AT ASCENSION ST. JOSEPH ON 25MAR2021 AND WAS ADMITTED AT THE TIME FOR SUICIDAL IDEATIONS. SHE WAS RELEASED ON 28MAY2021 WITH NEW MEDICATION FOR ANXIETY AND WAS SET UP FOR OUTPATIENT THERAPY SEEN FOR FIRST THERAPY YESTERDAY. SUBJECT HAS A HISTORY OF PSYCHIATRIC DISORDERS (ANXIETY, DEPRESSION, INSOMNIA, ATTENTION DEFICIT HYPERACTIVITY DISORDER) WILL ASK SUBJECT FOR PERMISSION TO OBTAIN RECORDS, WILL UPDATED SAE ONCE RECORDS ARE AVAILABLE. FOLLOWUP OF RECORDS RECEIVED AND REVIEWED. SUBJECT VOLUNTARILY TOOK HERSELF TO THE EMERGENCY ROOM TO

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SEEK HELP AFTER SHE WAS
EXPERIENCING
OVERWHELMING GRIEF AND
FEELING (b) (6)
(b) (6) SHE WAS
HAVING THOUGHTS OF
SUICIDE AND WISHING TO BE
DEAD FOR TWO WEEKS PRIOR.
SHE DID REPORT A PLAN AND
INTENT FOR SUICIDE WHILE
OUT OF THE HOSPITAL BUT
ONLY SUICIDAL THOUGHTS
ONCE ADMITTED. URINE DRUG
SCREEN ON ADMISSION WAS
ONLY POSITIVE FOR
AMPHETAMINES, (SHE IS
PRESCRIBED VYVANSE).
SUBJECT'S GRIEF AND STRESS
PRIMARILY RELATED TO
DEATH OF (b) (6)
(b) (6) DURING
HOSPITALIZATION, SHE
ATTENDED GROUP THERAPY
SESSIONS, INDIVIDUAL
THERAPY SESSIONS, AND
IMPROVED BASELINE ANXIETY
AND DEPRESSION. SHE WAS
STARTED ON BUSPIRONE AND
HYDROXYZINE AND
DISCHARGED ON THESE
MEDICATIONS. HER HOME
MEDICATIONS SHE WAS
TAKING FOR HER PREVIOUSLY
DIAGNOSED PSYCHIATRIC

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

CONDITIONS WERE
CONTINUED DURING THE
COURSE OF HER STAY AND
UPON DISCHARGE. SHE WAS
DISCHARGED 28MAR2021 TO
HOME WITH HUSBAND AND
FOLLOWUP APPOINTMENTS
SCHEDULED FOR OUTPATIENT
INDIVIDUAL AND COUPLE'S
THERAPY.

RELEVANT MEDICAL HISTORY
OF ANXIETY, DEPRESSION,
INSOMNIA AND ATTENTION
DEFICIT HYPERACTIVITY
DISORDER.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 07:06:35

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Mar 2021 20:10:23

Generated On: 10 Jun 2021 08:18:28

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication MIRENA

Prophylaxis Yes ☐
No ☒

Indication CONTRACEPTION

Dose per administration 52

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

EVERY THREE YEARS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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 checked="" type="checkbox"/>
If route of administration is Other, specify		INTRA-UTERINE
Start date (dd MMM yyyy)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication VYVANSE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)		01 JAN 2016
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2005
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication OMEGA 3

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 520

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication PRISTIQ

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication B12

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		SUBLINGUAL
Start date (dd MMM yyyy)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication DOXEPIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUL 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)	5 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 5 SEP 2020		
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)		06 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)		06 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication TERBINIFATE

Prophylaxis Yes ☐
No ☒

Indication ECZEMA GENERALIZED

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 AUG 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication PEPTO-BISMOL

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 1500

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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US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 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"/>

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication BUSPAR

Prophylaxis Yes ☐
No ☒

Indication MAJOR DEPRESSIVE DISORDER,
SEVERE, RECURRENT

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)	25 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication MAJOR DEPRESSIVE DISORDER,
SEVERE, RECURRENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:45:47

Generated On: 10 Jun 2021 08:18:28

	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)		25 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3592061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 25 Mar 2021 20:10:23

Generated On: 10 Jun 2021 08:18:28

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3592061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:18:28

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3592061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:28

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 ☐

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SAEID	USA-US103-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SAEID	USA-US103-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/APR/2021 12:54
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

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SAEID	USA-US103-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 13:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:06:35

Generated On: 10 Jun 2021 08:18:28

SAEID	USA-US103-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERRY
Investigator's Last Name	POLING
Site Address: Street	1709 S ROCK RD
Site Address: City	WICHITA
Site Address: State	KS
Site Address: Postal Code	67207
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/APR/2021 10:08
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

Audit

US3592061 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592061

Form: Participant Creation

Generated On: 10 Jun 2021 08:18:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:24:06
User entered 'US3592061'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:28

US3592061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 14:48:22

US3592061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:39
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:29

US3592061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Aug 2020 14:48:22

US3592061

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'SCRN'	System	08 Aug 2020 14:48:22

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:30

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '44'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'YEARS'	System	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '44'	System	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered 'Female (F)'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered 'l'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	30 Oct 2020 21:01:51
User entered '0'	(D) (4), (D) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	30 Oct 2020 21:01:51
User entered '0'	(D) (4), (D) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:51
User entered '0'	(b) (4), (b) (6)	08 Aug 2020 14:48:37

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Aug 2020'	System	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '2020'	System	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered 'No (N)'	(b) (4), (b) (6)	08 Aug 2020 14:48:49

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:01:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:29

US3592061

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'l'	System	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:18:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:22:17

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User closed query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:43:17
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4) (b) (4)	30 Sep 2020 15:25:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:25:57
Data point term sent to Coder	System	30 Sep 2020 15:25:11
Query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'location added to term ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:25:01
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 15:24:53
User entered 'MYOPIA bilateral' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 15:24:53
User opened query 'Per DM CLR: Please specify the location of MYOPIA (e.g. right, left or in both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:13:16
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4) (b) (4)	09 Aug 2020 20:25:38

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Aug 2020 20:25:38
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Aug 2020 20:24:03
User entered 'Myopia'	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 1989'	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 1989'	System	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '1989'	System	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:23:42

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 07:05:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 07:05:26
Data point term sent to Coder	System	09 Aug 2020 20:24:05
User entered 'Bilateral astigmatism'	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 1989'	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 1989'	System	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '1989'	System	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:23:56

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:25:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:25:38
Data point term sent to Coder	System	09 Aug 2020 20:25:05
User entered 'Seasonal allergies'	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:12:34
User entered 'UN Jan 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:12:34
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 2018'	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 2018'	System	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '2018'	System	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:24:09

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User closed query 'Per DM CLR: Please specify the location of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:49:26
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:27:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:27:02
Data point term sent to Coder	System	30 Sep 2020 15:26:14
Query 'Per DM CLR: Please specify the location of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'term updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 15:25:24
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 15:25:18
User entered 'ECZEMA generalized' reason for change: New Information	(b) (4), (b) (6)	30 Sep 2020 15:25:18
User opened query 'Per DM CLR: Please specify the location of ECZEMA. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:13:37
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:25:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:25:38
Data point term sent to Coder	System	09 Aug 2020 20:25:06

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
User entered 'Eczema'	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 2018'	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 2018'	System	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '2018'	System	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:24:22

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
Data point term sent to Coder	System	09 Aug 2020 20:26:06
User entered 'Migraines'	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 1983'	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 1983'	System	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '1983'	System	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:10

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
Data point term sent to Coder	System	09 Aug 2020 20:26:07
User entered 'Anxiety'	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 1985'	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 1985'	System	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '1985'	System	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:23

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
Data point term sent to Coder	System	09 Aug 2020 20:26:07
User entered 'Depression'	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 1985'	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 1985'	System	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '1985'	System	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:36

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:26:38
Data point term sent to Coder	System	09 Aug 2020 20:26:07
User entered 'Insomnia'	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:14:21
User entered 'UN Jan 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:14:21
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 2005'	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 2005'	System	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '2005'	System	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:25:51

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:27:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Aug 2020 20:27:38
Data point term sent to Coder	System	09 Aug 2020 20:27:07
User entered 'Attention deficit hyperactivity disorder'	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'un UNK 2016'	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:25
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'Jan 2016'	System	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '2016'	System	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:26:09

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered '08:52'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '8 Aug 2020 08:52'	System	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered '170.0' cm	(b) (4), (b) (6)	09 Aug 2020 20:27:10
DataPoint set to visible.	System	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered '105.8' kg	(b) (4), (b) (6)	09 Aug 2020 20:27:10
DataPoint set to visible.	System	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
Amendment Manager: User entered '36.60900'	System	16 Sep 2020 23:48:39
User entered '36.6'	System	09 Aug 2020 20:27:10
DataPoint set to visible.	System	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'kg/m2'	System	09 Aug 2020 20:27:10
DataPoint set to visible.	System	08 Aug 2020 14:48:55

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 03:14:17
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 16:04:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 03:37:23
User entered '98.9' F	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User entered 'Oral (Oral)'		09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User entered '62'		09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'bpm'	System	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User entered '16'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'breaths/min'	System	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User entered '109'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:28
User entered '71'	(b) (4), (b) (6)	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	09 Aug 2020 20:27:10

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32

US3592061

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32

US3592061

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:46:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:31:50

US3592061

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:42
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:37:05
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:37:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:46:57
User entered '8 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:46:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 16:04:04
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:31:50

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:28

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:48
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:12

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered 'Urine (URINE)'	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:24:55
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	09 Aug 2020 20:32:34

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered 'l'	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:36
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:32:57

US3592061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:33:08

US3592061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:43
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:33:08

US3592061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Aug 2020 20:33:08

US3592061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'VISIT1'	System	09 Aug 2020 20:33:08

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:34

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:04:51
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:04:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 14:35:34
User entered '102295' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:34

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:35:34

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:33

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:33

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:33

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:33

US3592061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:02:51
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 19:09:33

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '170.0' cm	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '105.8' kg	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '170.0' cm	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '105.8' kg	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '08:52'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '8 Aug 2020 08:52'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '98.9' F	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '62'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'bpm'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '16'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'breaths/min'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '109'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '71'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '170.0' cm	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 23:55:15
User entered '105.8' kg	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Post-Dose (POSTDOSE)'		09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 05:57:12
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:35:08
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		09 Aug 2020 20:34:55
User entered '10:11'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '8 Aug 2020 10:11'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '96.9' F	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '66'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'bpm'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '16'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'breaths/min'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '107'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:23
User entered '72'	(b) (4), (b) (6)	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	09 Aug 2020 20:34:55

US3592061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:47:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:35:16

US3592061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:47:13
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:35:16

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:00:18
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'changed to no ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 13:46:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:46:25
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:16:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:46:25
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:46:25
User entered 'Urine (URINE)'	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:46:25
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:05
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered empty.	System	09 Aug 2020 20:35:36

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered empty.	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered '8 Aug 2020'	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered '09:42'	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '8 Aug 2020 09:42'	System	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:26:38
User entered 'ONCE'	System	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 14:49:24

US3592061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:36:50

US3592061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:10
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:36:50

US3592061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:10
User entered '09:10'	(b) (4), (b) (6)	09 Aug 2020 20:36:50

US3592061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '8 Aug 2020 09:10'	System	09 Aug 2020 20:36:50

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:14
User entered '8 Aug 2020'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:14
User entered '09:14'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '8 Aug 2020 09:14'	System	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:14
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:14
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered empty.	System	09 Aug 2020 20:37:07

US3592061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:37:13

US3592061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	09 Aug 2020 20:37:13

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:20:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd107743e-f79f-41bc-991a-3498f3ad4861'	System	08 Aug 2020 15:17:39
User entered 'Yes (Y)'	System	08 Aug 2020 15:17:39

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:20:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd107743e-f79f-41bc-991a-3498f3ad4861'	System	08 Aug 2020 15:17:39
User entered '96.9'	System	08 Aug 2020 15:17:39

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:20:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd107743e-f79f-41bc-991a-3498f3ad4861'	System	08 Aug 2020 15:17:39
User entered 'No (N)'	System	08 Aug 2020 15:17:39

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:20:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd107743e-f79f-41bc-991a-3498f3ad4861'	System	08 Aug 2020 15:17:39
User entered '08 Aug 2020 10:20'	System	08 Aug 2020 15:17:39

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 10:02'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 12:32'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:14:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f4d1a10-951d-446a-885d-f5ed0a04e8d6'	System	09 Aug 2020 02:11:44
User entered 'Yes (Y)'	System	09 Aug 2020 02:11:44

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:14:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f4d1a10-951d-446a-885d-f5ed0a04e8d6'	System	09 Aug 2020 02:11:44
User entered '97.6'	System	09 Aug 2020 02:11:44

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:14:54', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f4d1a10-951d-446a-885d-f5ed0a04e8d6'	System	09 Aug 2020 02:11:44
User entered 'No (N)'	System	09 Aug 2020 02:11:44

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:14:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f4d1a10-951d-446a-885d-f5ed0a04e8d6'	System	09 Aug 2020 02:11:44
User entered '08 Aug 2020 21:14'	System	09 Aug 2020 02:11:44

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 13:27'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 2'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:26:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '88b397a6-7be9-4c33-9b89-32eaf126203e'	System	10 Aug 2020 03:24:11
User entered 'Yes (Y)'	System	10 Aug 2020 03:24:11

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:13', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '88b397a6-7be9-4c33-9b89-32eaf126203e'	System	10 Aug 2020 03:24:11
User entered '97.1'	System	10 Aug 2020 03:24:11

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '88b397a6-7be9-4c33-9b89-32eaf126203e'	System	10 Aug 2020 03:24:11
User entered 'No (N)'	System	10 Aug 2020 03:24:11

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '88b397a6-7be9-4c33-9b89-32eaf126203e'	System	10 Aug 2020 03:24:11
User entered '09 Aug 2020 22:27'	System	10 Aug 2020 03:24:11

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 3'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:11:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1fbc556a-ac23-4c12-a885-9c9ad1d28e79'	System	11 Aug 2020 03:08:57
User entered 'Yes (Y)'	System	11 Aug 2020 03:08:57

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:02', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1fbc556a-ac23-4c12-a885-9c9ad1d28e79'	System	11 Aug 2020 03:08:57
User entered '97.0'	System	11 Aug 2020 03:08:57

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1fbc556a-ac23-4c12-a885-9c9ad1d28e79'	System	11 Aug 2020 03:08:57
User entered 'No (N)'	System	11 Aug 2020 03:08:57

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1fbc556a-ac23-4c12-a885-9c9ad1d28e79'	System	11 Aug 2020 03:08:57
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:08:57

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 4'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:15:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b39e60ae-5f27-4924-bac3-0a9b75dd6e39'	System	12 Aug 2020 03:13:46
User entered 'Yes (Y)'	System	12 Aug 2020 03:13:46

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:16:54', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b39e60ae-5f27-4924-bac3-0a9b75dd6e39'	System	12 Aug 2020 03:13:46
User entered '97.1'	System	12 Aug 2020 03:13:46

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:16:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b39e60ae-5f27-4924-bac3-0a9b75dd6e39'	System	12 Aug 2020 03:13:46
User entered 'No (N)'	System	12 Aug 2020 03:13:46

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:16:59', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b39e60ae-5f27-4924-bac3-0a9b75dd6e39'	System	12 Aug 2020 03:13:46
User entered '11 Aug 2020 22:16'	System	12 Aug 2020 03:13:46

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 5'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '057c9d0e-be27-4438-ba37-8d2a315da684'	System	13 Aug 2020 05:47:59
User entered 'Yes (Y)'	System	13 Aug 2020 05:47:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:06', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '057c9d0e-be27-4438-ba37-8d2a315da684'	System	13 Aug 2020 05:47:59
User entered '97.9'	System	13 Aug 2020 05:47:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '057c9d0e-be27-4438-ba37-8d2a315da684'	System	13 Aug 2020 05:47:59
User entered 'No (N)'	System	13 Aug 2020 05:47:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:11', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '057c9d0e-be27-4438-ba37-8d2a315da684'	System	13 Aug 2020 05:47:59
User entered '13 Aug 2020 00:51'	System	13 Aug 2020 05:47:59

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 6'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:01', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered 'Yes (Y)'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:06', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered '98.7'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:13', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered 'Yes (Y)'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User closed query 'Per CDM: Please confirm the line number on concomitant medication page to clarify medication taken to treat pain or fever of this day. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:33:13
Query 'Per CDM: Please confirm the line number on concomitant medication page to clarify medication taken to treat pain or fever of this day. Thank you.' answered with 'medication added' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:19:28
User opened query 'Per CDM: Please confirm the line number on concomitant medication page to clarify medication taken to treat pain or fever of this day. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 06:04:44
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Aug 2020 18:41:29
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication added' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 15:13:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 02:38:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered '1'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered '0'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '3f0cde11-2309-4104-9569-08b1945f69b1'	System	14 Aug 2020 02:38:56
User entered '13 Aug 2020 21:42'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 7'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '76dff3e6-5604-4306-857e-632bb60c39b6'	System	15 Aug 2020 05:25:07
User entered 'Yes (Y)'	System	15 Aug 2020 05:25:07

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '76dff3e6-5604-4306-857e-632bb60c39b6'	System	15 Aug 2020 05:25:07
User entered '97.9'	System	15 Aug 2020 05:25:07

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '76dff3e6-5604-4306-857e-632bb60c39b6'	System	15 Aug 2020 05:25:07
User entered 'No (N)'	System	15 Aug 2020 05:25:07

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '76dff3e6-5604-4306-857e-632bb60c39b6'	System	15 Aug 2020 05:25:07
User entered '15 Aug 2020 00:28'	System	15 Aug 2020 05:25:07

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1e5bc934-e4e3-4895-bb28-b945b9d041e3'	System	08 Aug 2020 15:18:47
User entered 'None (1)'	System	08 Aug 2020 15:18:47

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1e5bc934-e4e3-4895-bb28-b945b9d041e3'	System	08 Aug 2020 15:18:47
User entered 'No (N)'	System	08 Aug 2020 15:18:47

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1e5bc934-e4e3-4895-bb28-b945b9d041e3'	System	08 Aug 2020 15:18:47
User entered 'No (N)'	System	08 Aug 2020 15:18:47

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1e5bc934-e4e3-4895-bb28-b945b9d041e3'	System	08 Aug 2020 15:18:47
User entered 'None (1)'	System	08 Aug 2020 15:18:47

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:22:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1e5bc934-e4e3-4895-bb28-b945b9d041e3'	System	08 Aug 2020 15:18:47
User entered '08 Aug 2020 10:22'	System	08 Aug 2020 15:18:47

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 10:02'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 12:32'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:04', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f27d7bc-bb5a-4be2-afdf-97971561e821'	System	09 Aug 2020 02:12:16
User entered 'None (1)'	System	09 Aug 2020 02:12:16

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f27d7bc-bb5a-4be2-afdf-97971561e821'	System	09 Aug 2020 02:12:16
User entered 'No (N)'	System	09 Aug 2020 02:12:16

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f27d7bc-bb5a-4be2-afdf-97971561e821'	System	09 Aug 2020 02:12:16
User entered 'No (N)'	System	09 Aug 2020 02:12:16

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:25', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f27d7bc-bb5a-4be2-afdf-97971561e821'	System	09 Aug 2020 02:12:16
User entered 'None (1)'	System	09 Aug 2020 02:12:16

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f27d7bc-bb5a-4be2-afdf-97971561e821'	System	09 Aug 2020 02:12:16
User entered '08 Aug 2020 21:15'	System	09 Aug 2020 02:12:16

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 13:27'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 2'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '333cc3fc-6186-48d7-8266-8fc113403e6d'	System	10 Aug 2020 03:24:38
User entered 'None (1)'	System	10 Aug 2020 03:24:38

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '333cc3fc-6186-48d7-8266-8fc113403e6d'	System	10 Aug 2020 03:24:38
User entered 'No (N)'	System	10 Aug 2020 03:24:38

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '333cc3fc-6186-48d7-8266-8fc113403e6d'	System	10 Aug 2020 03:24:38
User entered 'No (N)'	System	10 Aug 2020 03:24:38

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:44', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '333cc3fc-6186-48d7-8266-8fc113403e6d'	System	10 Aug 2020 03:24:38
User entered 'None (1)'	System	10 Aug 2020 03:24:38

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '333cc3fc-6186-48d7-8266-8fc113403e6d'	System	10 Aug 2020 03:24:38
User entered '09 Aug 2020 22:27'	System	10 Aug 2020 03:24:38

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 3'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:11', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ab8d82d2-e4b8-4abb-af2d-a848988eb409'	System	11 Aug 2020 03:09:07
User entered 'None (1)'	System	11 Aug 2020 03:09:07

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ab8d82d2-e4b8-4abb-af2d-a848988eb409'	System	11 Aug 2020 03:09:07
User entered 'No (N)'	System	11 Aug 2020 03:09:07

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:15', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ab8d82d2-e4b8-4abb-af2d-a848988eb409'	System	11 Aug 2020 03:09:07
User entered 'No (N)'	System	11 Aug 2020 03:09:07

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:17', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ab8d82d2-e4b8-4abb-af2d-a848988eb409'	System	11 Aug 2020 03:09:07
User entered 'None (1)'	System	11 Aug 2020 03:09:07

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ab8d82d2-e4b8-4abb-af2d-a848988eb409'	System	11 Aug 2020 03:09:07
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:09:07

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 4'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:03', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c407541-d32d-4026-a5c2-99ba4d19ab6b'	System	12 Aug 2020 03:13:59
User entered 'None (1)'	System	12 Aug 2020 03:13:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c407541-d32d-4026-a5c2-99ba4d19ab6b'	System	12 Aug 2020 03:13:59
User entered 'No (N)'	System	12 Aug 2020 03:13:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c407541-d32d-4026-a5c2-99ba4d19ab6b'	System	12 Aug 2020 03:13:59
User entered 'No (N)'	System	12 Aug 2020 03:13:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c407541-d32d-4026-a5c2-99ba4d19ab6b'	System	12 Aug 2020 03:13:59
User entered 'None (1)'	System	12 Aug 2020 03:13:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:12', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c407541-d32d-4026-a5c2-99ba4d19ab6b'	System	12 Aug 2020 03:13:59
User entered '11 Aug 2020 22:17'	System	12 Aug 2020 03:13:59

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 5'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:15', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f5d6f99-6355-42fb-a67d-c1a59391fedf'	System	13 Aug 2020 05:48:12
User entered 'None (1)'	System	13 Aug 2020 05:48:12

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:17', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f5d6f99-6355-42fb-a67d-c1a59391fedf'	System	13 Aug 2020 05:48:12
User entered 'No (N)'	System	13 Aug 2020 05:48:12

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f5d6f99-6355-42fb-a67d-c1a59391fedf'	System	13 Aug 2020 05:48:12
User entered 'No (N)'	System	13 Aug 2020 05:48:12

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f5d6f99-6355-42fb-a67d-c1a59391fedf'	System	13 Aug 2020 05:48:12
User entered 'None (1)'	System	13 Aug 2020 05:48:12

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2f5d6f99-6355-42fb-a67d-c1a59391fedf'	System	13 Aug 2020 05:48:12
User entered '13 Aug 2020 00:51'	System	13 Aug 2020 05:48:12

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 6'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:46', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b3d7355a-67b4-4721-8d94-7d1653507f7e'	System	14 Aug 2020 02:39:29
User entered 'None (1)'	System	14 Aug 2020 02:39:29

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b3d7355a-67b4-4721-8d94-7d1653507f7e'	System	14 Aug 2020 02:39:29
User entered 'No (N)'	System	14 Aug 2020 02:39:29

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b3d7355a-67b4-4721-8d94-7d1653507f7e'	System	14 Aug 2020 02:39:29
User entered 'No (N)'	System	14 Aug 2020 02:39:29

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b3d7355a-67b4-4721-8d94-7d1653507f7e'	System	14 Aug 2020 02:39:29
User entered 'None (1)'	System	14 Aug 2020 02:39:29

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:42:55', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'b3d7355a-67b4-4721-8d94-7d1653507f7e'	System	14 Aug 2020 02:39:29
User entered '13 Aug 2020 21:42'	System	14 Aug 2020 02:39:29

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 7'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd85571af-a7c3-478b-9e0d-4a0f0afbc23f'	System	15 Aug 2020 05:25:22
User entered 'None (1)'	System	15 Aug 2020 05:25:22

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd85571af-a7c3-478b-9e0d-4a0f0afbc23f'	System	15 Aug 2020 05:25:22
User entered 'No (N)'	System	15 Aug 2020 05:25:22

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:41', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd85571af-a7c3-478b-9e0d-4a0f0afbc23f'	System	15 Aug 2020 05:25:22
User entered 'No (N)'	System	15 Aug 2020 05:25:22

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:43', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd85571af-a7c3-478b-9e0d-4a0f0afbc23f'	System	15 Aug 2020 05:25:22
User entered 'None (1)'	System	15 Aug 2020 05:25:22

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:28:46', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd85571af-a7c3-478b-9e0d-4a0f0afbc23f'	System	15 Aug 2020 05:25:22
User entered '15 Aug 2020 00:28'	System	15 Aug 2020 05:25:22

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:20:59', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:04', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:12', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'None (0)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:17', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered 'No (N)'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T10:21:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '2070bd7e-c5a3-4423-9223-f5ad4d4ace99'	System	08 Aug 2020 15:18:08
User entered '08 Aug 2020 10:21'	System	08 Aug 2020 15:18:08

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 10:02'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 12:32'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:36', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:41', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:43', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'None (0)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:48', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered 'No (N)'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-08T21:15:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '50e97369-b97e-40f0-be67-eb02a55b9213'	System	09 Aug 2020 02:12:38
User entered '08 Aug 2020 21:15'	System	09 Aug 2020 02:12:38

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Aug 2020 13:27'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 2'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:55', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:27:59', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:28:01', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:28:03', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'None (0)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:28:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered 'No (N)'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-09T22:28:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'de4fae7a-5f52-42a6-9b87-2251ebd91b8c'	System	10 Aug 2020 03:24:55
User entered '09 Aug 2020 22:28'	System	10 Aug 2020 03:24:55

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 3'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'None (0)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'No interference with activity (1)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'None (0)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'None (0)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'None (0)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'None (0)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered 'No (N)'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-10T22:12:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '94fa3541-3149-4eb6-ad43-7c42a7ba7979'	System	11 Aug 2020 03:09:35
User entered '10 Aug 2020 22:12'	System	11 Aug 2020 03:09:35

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 4'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:16', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:18', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'None (0)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered 'No (N)'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-11T22:17:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6b629075-d0f3-4e81-a5f3-33b1908f7177'	System	12 Aug 2020 03:14:20
User entered '11 Aug 2020 22:17'	System	12 Aug 2020 03:14:20

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 5'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:28', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:34', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'None (0)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered 'No (N)'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T00:51:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ba476dc8-7cb9-4e78-a5bb-b1b8d5a994ed'	System	13 Aug 2020 05:48:28
User entered '13 Aug 2020 00:51'	System	13 Aug 2020 05:48:28

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 6'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:16', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'None (0)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'None (0)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:28', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'None (0)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'None (0)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'None (0)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered 'No (N)'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-13T21:43:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '38fa49f5-907f-439a-82f5-70b8a3121ca3'	System	14 Aug 2020 02:40:12
User entered '13 Aug 2020 21:43'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 7'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:02', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'None (0)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:03', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'None (0)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'None (0)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'None (0)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:11', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered 'No (N)'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-15T00:29:13', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dbd2a8bc-5e48-4d2b-9517-cc3df9f85316'	System	15 Aug 2020 05:25:47
User entered '15 Aug 2020 00:29'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	14 Aug 2020 02:40:12
User entered 'Day 8'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '0cf61cb8-f8ac-4ece-8a1b-745f4dba77ea'	System	16 Aug 2020 04:57:11
User entered 'No interference with activity (1)'	System	16 Aug 2020 04:57:11

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '0cf61cb8-f8ac-4ece-8a1b-745f4dba77ea'	System	16 Aug 2020 04:57:11
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:57:11

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 02:40:12

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	15 Aug 2020 05:25:47
User entered 'Day 9'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-17T05:39:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8c9a60ae-1c35-4820-b7de-7ffdbb9589f1'	System	17 Aug 2020 10:35:53
User entered 'None (0)'	System	17 Aug 2020 10:35:53

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-17T05:39:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8c9a60ae-1c35-4820-b7de-7ffdbb9589f1'	System	17 Aug 2020 10:35:53
User entered '17 Aug 2020 05:39'	System	17 Aug 2020 10:35:53

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	15 Aug 2020 05:25:47
User entered 'Day 8'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:44', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fa264fd1-0c82-43b6-9b36-9ce6cf767469'	System	16 Aug 2020 04:57:21
User entered 'None (0)'	System	16 Aug 2020 04:57:21

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fa264fd1-0c82-43b6-9b36-9ce6cf767469'	System	16 Aug 2020 04:57:21
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:57:21

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 05:25:47

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	14 Aug 2020 02:38:56
User entered 'Day 8'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e465e607-d449-4a95-87d0-5280027f3ecd'	System	16 Aug 2020 04:57:32
User entered 'No (N)'	System	16 Aug 2020 04:57:32

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-08-16T00:00:55', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e465e607-d449-4a95-87d0-5280027f3ecd'	System	16 Aug 2020 04:57:32
User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:57:32

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 02:38:56

US3592061

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 02:38:56

US3592061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:47:39

US3592061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:56
User entered '16 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:47:39

US3592061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Aug 2020 14:47:39

US3592061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:26:56
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:47:39

US3592061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:34:03

US3592061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'l'	System	25 Aug 2020 14:34:03

US3592061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:35:11

US3592061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:05
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:35:11

US3592061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Aug 2020 14:35:11

US3592061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:05
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:35:11

US3592061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:35:39

US3592061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'l'	System	25 Aug 2020 14:35:39

US3592061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:10:01

US3592061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:20
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 19:10:01

US3592061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 19:10:01

US3592061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:20
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:10:01

US3592061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 19:10:05

US3592061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'l'	System	31 Aug 2020 19:10:05

US3592061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:39:54

US3592061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:42
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:39:54

US3592061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Sep 2020 13:39:54

US3592061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'VISIT2'	System	07 Sep 2020 13:39:54

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '07:54'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Sep 2020 07:54'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '98.1' F	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '72'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'bpm'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '18'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'breaths/min'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Sep 2020 13:47:44
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	07 Sep 2020 13:47:44
User entered '108' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:47:44
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	07 Sep 2020 13:41:53
User entered '168'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '74'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '09:23'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Sep 2020 09:23'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '98.2' F	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '68'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'bpm'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '16'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'breaths/min'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '114'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:27:53
User entered '78'	(b) (4), (b) (6)	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	07 Sep 2020 13:41:53

US3592061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:40:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:01
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:40:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered 'Urine (URINE)'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO", but the collection date and time has been provided. Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:02:39
Query 'Per CDM: Please note the FSH sample collected is answered as "NO", but the collection date and time has been provided. Kindly update appropriately.' answered with 'information removed ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:27:39
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO", but the collection date and time has been provided. Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 08:36:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:43:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Sep 2020 13:43:48
User entered 'No (N)'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:27:27
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:27:27
User entered '08:09'	(b) (4), (b) (6)	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered empty.	System	14 Sep 2020 16:27:27
User entered '5 Sep 2020 08:09'	System	07 Sep 2020 13:43:35

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'MRNA-1273 OR PLACEBO'	System	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered '5 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered '08:51'	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Sep 2020 08:51'	System	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:28:18
User entered 'ONCE'	System	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'INTRAMUSCULAR'	System	05 Sep 2020 13:56:00

US3592061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:42:18

US3592061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:49
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:42:18

US3592061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:03:49
User entered '08:14'	(b) (4), (b) (6)	07 Sep 2020 13:42:18

US3592061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Sep 2020 08:14'	System	07 Sep 2020 13:42:18

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:01
User entered '5 Sep 2020'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:01
User entered '08:15'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Sep 2020 08:15'	System	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:01
User entered 'No (N)'	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:01
User entered empty.	(b) (4), (b) (6)	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered empty.	System	07 Sep 2020 13:42:32

US3592061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Sep 2020 13:42:39

US3592061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	07 Sep 2020 13:42:39

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:27:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '49ea4bb2-9107-4d95-b51e-cfe35be8a71b'	System	05 Sep 2020 14:24:11
User entered 'Yes (Y)'	System	05 Sep 2020 14:24:11

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:27:36', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '49ea4bb2-9107-4d95-b51e-cfe35be8a71b'	System	05 Sep 2020 14:24:11
User entered '98.2'	System	05 Sep 2020 14:24:11

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:27:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '49ea4bb2-9107-4d95-b51e-cfe35be8a71b'	System	05 Sep 2020 14:24:11
User entered 'No (N)'	System	05 Sep 2020 14:24:11

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:27:41', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '49ea4bb2-9107-4d95-b51e-cfe35be8a71b'	System	05 Sep 2020 14:24:11
User entered '05 Sep 2020 09:27'	System	05 Sep 2020 14:24:11

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 09:11'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 11:41'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:03', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '79586d80-8b5a-41df-ac39-a7fedde5fb67'	System	06 Sep 2020 13:04:47
User entered 'Yes (Y)'	System	06 Sep 2020 13:04:47

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:10', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '79586d80-8b5a-41df-ac39-a7fedde5fb67'	System	06 Sep 2020 13:04:47
User entered '98.1'	System	06 Sep 2020 13:04:47

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '79586d80-8b5a-41df-ac39-a7fedde5fb67'	System	06 Sep 2020 13:04:47
User entered 'No (N)'	System	06 Sep 2020 13:04:47

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:16', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '79586d80-8b5a-41df-ae39-a7fedde5fb67'	System	06 Sep 2020 13:04:47
User entered '06 Sep 2020 08:08'	System	06 Sep 2020 13:04:47

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 12:36'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 2'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:48:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered 'Yes (Y)'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:04', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered '98.5'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:12', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered 'Yes (Y)'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medications are recorded on ConMed' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 04:20:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 22:16:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered '1'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered '0'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7e5734b7-a85c-40c2-bb35-130074b3d167'	System	07 Sep 2020 11:45:51
User entered '07 Sep 2020 06:49'	System	07 Sep 2020 11:45:51

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 3'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 4'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '605aa89a-b0ce-4b3b-82cb-72946920d470'	System	09 Sep 2020 03:05:03
User entered 'Yes (Y)'	System	09 Sep 2020 03:05:03

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '605aa89a-b0ce-4b3b-82cb-72946920d470'	System	09 Sep 2020 03:05:03
User entered '97.9'	System	09 Sep 2020 03:05:03

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '605aa89a-b0ce-4b3b-82cb-72946920d470'	System	09 Sep 2020 03:05:03
User entered 'No (N)'	System	09 Sep 2020 03:05:03

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '605aa89a-b0ce-4b3b-82cb-72946920d470'	System	09 Sep 2020 03:05:03
User entered '08 Sep 2020 22:08'	System	09 Sep 2020 03:05:03

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 5'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '83564b38-e5b7-467f-b28e-2e1e287ed784'	System	10 Sep 2020 01:26:46
User entered 'Yes (Y)'	System	10 Sep 2020 01:26:46

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:25', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '83564b38-e5b7-467f-b28e-2e1e287ed784'	System	10 Sep 2020 01:26:46
User entered '98.4'	System	10 Sep 2020 01:26:46

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '83564b38-e5b7-467f-b28e-2e1e287ed784'	System	10 Sep 2020 01:26:46
User entered 'No (N)'	System	10 Sep 2020 01:26:46

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '83564b38-e5b7-467f-b28e-2e1e287ed784'	System	10 Sep 2020 01:26:46
User entered '09 Sep 2020 20:30'	System	10 Sep 2020 01:26:46

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 6'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:08', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '17cafd8f-ac3d-4613-aa35-501fcd705fbc'	System	11 Sep 2020 01:46:38
User entered 'Yes (Y)'	System	11 Sep 2020 01:46:38

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '17cafd8f-ac3d-4613-aa35-501fcd705fbc'	System	11 Sep 2020 01:46:38
User entered '98.5'	System	11 Sep 2020 01:46:38

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '17cafd8f-ac3d-4613-aa35-501fcd705fbc'	System	11 Sep 2020 01:46:38
User entered 'No (N)'	System	11 Sep 2020 01:46:38

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:24', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '17cafd8f-ac3d-4613-aa35-501fcd705fbc'	System	11 Sep 2020 01:46:38
User entered '10 Sep 2020 20:50'	System	11 Sep 2020 01:46:38

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 7'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:36', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f6bf3ff-387b-4027-946d-526d2947cbd9'	System	12 Sep 2020 13:57:01
User entered 'Yes (Y)'	System	12 Sep 2020 13:57:01

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f6bf3ff-387b-4027-946d-526d2947cbd9'	System	12 Sep 2020 13:57:01
User entered '98.2'	System	12 Sep 2020 13:57:01

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:43', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f6bf3ff-387b-4027-946d-526d2947cbd9'	System	12 Sep 2020 13:57:01
User entered 'No (N)'	System	12 Sep 2020 13:57:01

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '8f6bf3ff-387b-4027-946d-526d2947cbd9'	System	12 Sep 2020 13:57:01
User entered '12 Sep 2020 09:00'	System	12 Sep 2020 13:57:01

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:01', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1c1c9290-e565-4089-9498-0c13955e51c2'	System	05 Sep 2020 14:24:40
User entered 'None (1)'	System	05 Sep 2020 14:24:40

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:04', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1c1c9290-e565-4089-9498-0c13955e51c2'	System	05 Sep 2020 14:24:40
User entered 'No (N)'	System	05 Sep 2020 14:24:40

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1c1c9290-e565-4089-9498-0c13955e51c2'	System	05 Sep 2020 14:24:40
User entered 'No (N)'	System	05 Sep 2020 14:24:40

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1c1c9290-e565-4089-9498-0c13955e51c2'	System	05 Sep 2020 14:24:40
User entered 'None (1)'	System	05 Sep 2020 14:24:40

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1c1c9290-e565-4089-9498-0c13955e51c2'	System	05 Sep 2020 14:24:40
User entered '05 Sep 2020 09:28'	System	05 Sep 2020 14:24:40

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 09:11'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 11:41'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'c90c1e14-ac91-42b4-9ad5-1d301f7d3e9e'	System	06 Sep 2020 13:04:57
User entered 'None (1)'	System	06 Sep 2020 13:04:57

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'c90c1e14-ac91-42b4-9ad5-1d301f7d3e9e'	System	06 Sep 2020 13:04:57
User entered 'No (N)'	System	06 Sep 2020 13:04:57

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:25', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'c90c1e14-ac91-42b4-9ad5-1d301f7d3e9e'	System	06 Sep 2020 13:04:57
User entered 'No (N)'	System	06 Sep 2020 13:04:57

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'c90c1e14-ac91-42b4-9ad5-1d301f7d3e9e'	System	06 Sep 2020 13:04:57
User entered 'None (1)'	System	06 Sep 2020 13:04:57

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'c90c1e14-ac91-42b4-9ad5-1d301f7d3e9e'	System	06 Sep 2020 13:04:57
User entered '06 Sep 2020 08:08'	System	06 Sep 2020 13:04:57

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 12:36'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 2'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '22c7cb19-0a19-4607-83bd-80d3152e5ea8'	System	07 Sep 2020 11:46:08
User entered 'None (1)'	System	07 Sep 2020 11:46:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:34', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '22c7cb19-0a19-4607-83bd-80d3152e5ea8'	System	07 Sep 2020 11:46:08
User entered 'No (N)'	System	07 Sep 2020 11:46:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '22c7cb19-0a19-4607-83bd-80d3152e5ea8'	System	07 Sep 2020 11:46:08
User entered 'No (N)'	System	07 Sep 2020 11:46:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '22c7cb19-0a19-4607-83bd-80d3152e5ea8'	System	07 Sep 2020 11:46:08
User entered 'None (1)'	System	07 Sep 2020 11:46:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '22c7cb19-0a19-4607-83bd-80d3152e5ea8'	System	07 Sep 2020 11:46:08
User entered '07 Sep 2020 06:49'	System	07 Sep 2020 11:46:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 3'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 4'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:54', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6c9d8664-161c-45f3-abc9-ee49c7194f45'	System	09 Sep 2020 03:05:17
User entered 'None (1)'	System	09 Sep 2020 03:05:17

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:56', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6c9d8664-161c-45f3-abc9-ee49c7194f45'	System	09 Sep 2020 03:05:17
User entered 'No (N)'	System	09 Sep 2020 03:05:17

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6c9d8664-161c-45f3-abc9-ee49c7194f45'	System	09 Sep 2020 03:05:17
User entered 'No (N)'	System	09 Sep 2020 03:05:17

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:08:59', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6c9d8664-161c-45f3-abc9-ee49c7194f45'	System	09 Sep 2020 03:05:17
User entered 'None (1)'	System	09 Sep 2020 03:05:17

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:02', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6c9d8664-161c-45f3-abc9-ee49c7194f45'	System	09 Sep 2020 03:05:17
User entered '08 Sep 2020 22:09'	System	09 Sep 2020 03:05:17

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 5'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:32', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'cadedb11-eb6d-4a5f-9c46-3aa488237080'	System	10 Sep 2020 01:26:55
User entered 'None (1)'	System	10 Sep 2020 01:26:55

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'cadedb11-eb6d-4a5f-9c46-3aa488237080'	System	10 Sep 2020 01:26:55
User entered 'No (N)'	System	10 Sep 2020 01:26:55

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'cadedb11-eb6d-4a5f-9c46-3aa488237080'	System	10 Sep 2020 01:26:55
User entered 'No (N)'	System	10 Sep 2020 01:26:55

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'cadedb11-eb6d-4a5f-9c46-3aa488237080'	System	10 Sep 2020 01:26:55
User entered 'None (1)'	System	10 Sep 2020 01:26:55

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'cadedb11-eb6d-4a5f-9c46-3aa488237080'	System	10 Sep 2020 01:26:55
User entered '09 Sep 2020 20:30'	System	10 Sep 2020 01:26:55

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 6'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:28', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '60af0014-a71b-41ff-8cfb-4ffa9a8ed42b'	System	11 Sep 2020 01:46:54
User entered 'None (1)'	System	11 Sep 2020 01:46:54

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:29', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '60af0014-a71b-41ff-8cfb-4ffa9a8ed42b'	System	11 Sep 2020 01:46:54
User entered 'No (N)'	System	11 Sep 2020 01:46:54

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '60af0014-a71b-41ff-8cfb-4ffa9a8ed42b'	System	11 Sep 2020 01:46:54
User entered 'No (N)'	System	11 Sep 2020 01:46:54

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '60af0014-a71b-41ff-8cfb-4ffa9a8ed42b'	System	11 Sep 2020 01:46:54
User entered 'None (1)'	System	11 Sep 2020 01:46:54

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '60af0014-a71b-41ff-8cfb-4ffa9a8ed42b'	System	11 Sep 2020 01:46:54
User entered '10 Sep 2020 20:50'	System	11 Sep 2020 01:46:54

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 7'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:48', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '312299eb-27ef-41c0-b740-075835d9738a'	System	12 Sep 2020 13:57:08
User entered 'None (1)'	System	12 Sep 2020 13:57:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '312299eb-27ef-41c0-b740-075835d9738a'	System	12 Sep 2020 13:57:08
User entered 'No (N)'	System	12 Sep 2020 13:57:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '312299eb-27ef-41c0-b740-075835d9738a'	System	12 Sep 2020 13:57:08
User entered 'No (N)'	System	12 Sep 2020 13:57:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '312299eb-27ef-41c0-b740-075835d9738a'	System	12 Sep 2020 13:57:08
User entered 'None (1)'	System	12 Sep 2020 13:57:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:54', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '312299eb-27ef-41c0-b740-075835d9738a'	System	12 Sep 2020 13:57:08
User entered '12 Sep 2020 09:00'	System	12 Sep 2020 13:57:08

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:13', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'None (0)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'No interference with activity (1)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'None (0)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:24', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'None (0)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:26', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'None (0)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:28', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'None (0)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered 'No (N)'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-05T09:28:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '9e5397ce-ae20-41a9-8bd1-791167e9cbc6'	System	05 Sep 2020 14:25:02
User entered '05 Sep 2020 09:28'	System	05 Sep 2020 14:25:02

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 09:11'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 11:41'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 1, after vaccination (at home)'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:41', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'None (0)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:42', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'None (0)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:44', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'None (0)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'None (0)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered 'No (N)'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-06T08:08:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c824eaf-bb7a-46ba-b340-63b3685e7813'	System	06 Sep 2020 13:05:18
User entered '06 Sep 2020 08:08'	System	06 Sep 2020 13:05:18

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '05 Sep 2020 12:36'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 2'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:48', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'No interference with activity (1)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:49:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'None (0)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:50:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'None (0)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:50:05', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:50:08', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'None (0)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:50:10', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered 'No (N)'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-07T06:50:12', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6fa83fb6-db79-42ff-a2bd-be110a742b14'	System	07 Sep 2020 11:46:42
User entered '07 Sep 2020 06:50'	System	07 Sep 2020 11:46:42

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 3'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 4'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:11', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:12', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:15', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'None (0)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:18', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered 'No (N)'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-08T22:09:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '231a1a99-1999-41dd-b2df-af1d20ebd851'	System	09 Sep 2020 03:05:37
User entered '08 Sep 2020 22:09'	System	09 Sep 2020 03:05:37

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '08 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 5'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:44', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:46', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:52', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'None (0)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:56', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered 'No (N)'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-09T20:30:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '065746e4-3065-46ba-8207-da754c329dfd'	System	10 Sep 2020 01:27:14
User entered '09 Sep 2020 20:30'	System	10 Sep 2020 01:27:14

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '09 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 6'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:42', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:43', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:46', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'None (0)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:49', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered 'No (N)'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-10T20:50:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fc846124-908d-495b-aac2-793dd8766239'	System	11 Sep 2020 01:47:05
User entered '10 Sep 2020 20:50'	System	11 Sep 2020 01:47:05

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '10 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	05 Sep 2020 13:56:00
User entered 'Day 7'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:00:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:01', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:02', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:04', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'None (0)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:06', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered 'No (N)'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-09-12T09:01:08', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ac1beb90-c1d0-4e6b-80b9-d953d3d14038'	System	12 Sep 2020 13:57:22
User entered '12 Sep 2020 09:01'	System	12 Sep 2020 13:57:22

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '11 Sep 2020 12:00'	System	05 Sep 2020 13:56:00

US3592061

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User entered '12 Sep 2020 11:59'	System	05 Sep 2020 13:56:00

US3592061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:28:32

US3592061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:41
User entered '13 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:28:32

US3592061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 16:28:32

US3592061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:41
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:28:32

US3592061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:18:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:28:37

US3592061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	14 Sep 2020 16:28:37

US3592061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Sep 2020 17:06:11

US3592061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:52
User entered '20 Sep 2020'	(b) (4), (b) (6)	20 Sep 2020 17:06:11

US3592061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Sep 2020 17:06:11

US3592061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:28:52
User entered empty.	(b) (4), (b) (6)	20 Sep 2020 17:06:11

US3592061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:48:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Sep 2020 17:06:16

US3592061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	20 Sep 2020 17:06:16

US3592061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 21:35:36

US3592061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:00
User entered '26 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 21:35:36

US3592061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 21:35:36

US3592061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:00
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 21:35:36

US3592061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 21:35:40

US3592061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	28 Sep 2020 21:35:40

US3592061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:56:14

US3592061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:37
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:56:14

US3592061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Oct 2020 20:56:14

US3592061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'VISIT3'	System	05 Oct 2020 20:56:14

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '14:38'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Oct 2020 14:38'	System	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '98.8' F	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '78'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'bpm'	System	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '16'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'breaths/min'	System	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '113'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:17
User entered '76'	(b) (4), (b) (6)	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'mmHg'	System	05 Oct 2020 20:56:39

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56

US3592061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56

US3592061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:21
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 20:56:44

US3592061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:21
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:56:44

US3592061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:57:00

US3592061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:41
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:57:00

US3592061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:41
User entered '14:57'	(b) (4), (b) (6)	05 Oct 2020 20:57:00

US3592061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered '5 Oct 2020 14:57'	System	05 Oct 2020 20:57:00

US3592061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:03:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:56:48

US3592061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'I'	System	05 Oct 2020 20:56:48

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 64'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-10T08:28:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1b50b7d6-1469-408f-8a9b-b20dd6ac238f'	System	10 Oct 2020 13:24:23
User entered 'No (N)'	System	10 Oct 2020 13:24:23

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-10T08:28:24', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1b50b7d6-1469-408f-8a9b-b20dd6ac238f'	System	10 Oct 2020 13:24:23
User entered 'No (N)'	System	10 Oct 2020 13:24:23

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-10T08:28:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1b50b7d6-1469-408f-8a9b-b20dd6ac238f' User entered '10 Oct 2020 08:28:27'	System	10 Oct 2020 13:24:23
	System	10 Oct 2020 13:24:23

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 71'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-16T11:18:09', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '962b5b21-1867-4272-ae07-c99f1a2ac4e5'	System	16 Oct 2020 16:14:19
User entered 'No (N)'	System	16 Oct 2020 16:14:19

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-16T11:18:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '962b5b21-1867-4272-ae07-c99f1a2ac4e5'	System	16 Oct 2020 16:14:19
User entered 'No (N)'	System	16 Oct 2020 16:14:19

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-16T11:18:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '962b5b21-1867-4272-ae07-c99f1a2ac4e5'	System	16 Oct 2020 16:14:19
User entered '16 Oct 2020 11:18:23'	System	16 Oct 2020 16:14:19

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 78'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-23T20:11:06', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fe7f4234-ea1e-4e92-94de-6a15e25e3d4e'	System	24 Oct 2020 01:06:55
User entered 'No (N)'	System	24 Oct 2020 01:06:55

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-23T20:11:10', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fe7f4234-ea1e-4e92-94de-6a15e25e3d4e'	System	24 Oct 2020 01:06:55
User entered 'No (N)'	System	24 Oct 2020 01:06:55

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-10-23T20:11:13', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fe7f4234-ea1e-4e92-94de-6a15e25e3d4e'	System	24 Oct 2020 01:06:55
User entered '23 Oct 2020 20:11:13'	System	24 Oct 2020 01:06:55

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 92'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-05T06:47:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '419b47ee-544a-4708-8a69-42fc61fe66b5'	System	05 Nov 2020 12:42:57
User entered 'No (N)'	System	05 Nov 2020 12:42:57

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-05T06:47:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '419b47ee-544a-4708-8a69-42fc61fe66b5'	System	05 Nov 2020 12:42:57
User entered 'No (N)'	System	05 Nov 2020 12:42:57

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-05T06:47:16', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '419b47ee-544a-4708-8a69-42fc61fe66b5'	System	05 Nov 2020 12:42:57
User entered '05 Nov 2020 06:47:16'	System	05 Nov 2020 12:42:57

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 99'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:22:30', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'Yes (Y)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:22:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'Yes (Y)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:22:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:22:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'Yes (Y)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '1'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '0'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:31', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '1'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:34', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered 'No (N)'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-13T10:23:42', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '74356147-95df-4c05-8d9e-92dc080d4727'	System	13 Nov 2020 16:19:18
User entered '13 Nov 2020 10:23:42'	System	13 Nov 2020 16:19:18

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered 'Day 106'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:32:55
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE is not warranted ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 14:49:21
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 11:01:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'Yes (Y)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:15', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'Yes (Y)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:33', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'No (N)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:46', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'Yes (Y)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-19T02:15:52', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd005447b-f427-4d77-901f-4ba2bd7e51fb'	System	19 Nov 2020 08:11:28
User entered '19 Nov 2020 02:15:52'	System	19 Nov 2020 08:11:28

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 14:49:24

US3592061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:53:30
Data entry locked.	System	08 Aug 2020 14:49:24
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 14:49:24

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-11-26T22:58:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered 'Yes (Y)'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-11-26T22:58:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered 'No (N)'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-26T22:58:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered 'No (N)'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-26T22:58:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered 'Yes (Y)'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-26T22:59:01', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-26T22:59:07', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '489d4671-61bc-4d01-b3d3-2e2562174952'	System	27 Nov 2020 04:54:29
User entered '26 Nov 2020 22:59:07'	System	27 Nov 2020 04:54:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-11-30T06:58:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fdf495b8-3d12-4fd7-a20f-41952e20c04e'	System	30 Nov 2020 12:53:57
User entered 'No (N)'	System	30 Nov 2020 12:53:57

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-11-30T06:58:41', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fdf495b8-3d12-4fd7-a20f-41952e20c04e'	System	30 Nov 2020 12:53:57
User entered 'No (N)'	System	30 Nov 2020 12:53:57

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-11-30T06:58:44', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'fdf495b8-3d12-4fd7-a20f-41952e20c04e'	System	30 Nov 2020 12:53:57
User entered '30 Nov 2020 06:58:44'	System	30 Nov 2020 12:53:57

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-12-09T10:33:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '4d6284b5-6457-4711-9664-0e426e2ef920'	System	09 Dec 2020 16:33:54
User entered 'No (N)'	System	09 Dec 2020 16:33:54

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-12-09T10:33:48', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '4d6284b5-6457-4711-9664-0e426e2ef920'	System	09 Dec 2020 16:33:54
User entered 'No (N)'	System	09 Dec 2020 16:33:54

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-12-09T10:33:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '4d6284b5-6457-4711-9664-0e426e2ef920'	System	09 Dec 2020 16:33:54
User entered '09 Dec 2020 10:33:51'	System	09 Dec 2020 16:33:54

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-12-14T00:01:21', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ece5b886-e43c-4b73-b278-6ba0df3791ce'	System	14 Dec 2020 06:01:31
User entered 'No (N)'	System	14 Dec 2020 06:01:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-12-14T00:01:24', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ece5b886-e43c-4b73-b278-6ba0df3791ce'	System	14 Dec 2020 06:01:31
User entered 'No (N)'	System	14 Dec 2020 06:01:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-12-14T00:01:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ece5b886-e43c-4b73-b278-6ba0df3791ce' User entered '14 Dec 2020 00:01:27'	System	14 Dec 2020 06:01:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-12-21T04:07:53', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ffe6591d-321a-419c-8a7e-c6f7539c0406'	System	21 Dec 2020 10:08:06
User entered 'No (N)'	System	21 Dec 2020 10:08:06

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-12-21T04:07:58', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ffe6591d-321a-419c-8a7e-c6f7539c0406'	System	21 Dec 2020 10:08:06
User entered 'No (N)'	System	21 Dec 2020 10:08:06

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-12-21T04:08:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ffe6591d-321a-419c-8a7e-c6f7539c0406'	System	21 Dec 2020 10:08:06
User entered '21 Dec 2020 04:08:00'	System	21 Dec 2020 10:08:06

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2020-12-28T20:48:57', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '19efdef7-e4d6-47a8-a844-c4ab39517658'	System	29 Dec 2020 02:49:05
User entered 'No (N)'	System	29 Dec 2020 02:49:05

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2020-12-28T20:49:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '19efdef7-e4d6-47a8-a844-c4ab39517658'	System	29 Dec 2020 02:49:05
User entered 'No (N)'	System	29 Dec 2020 02:49:05

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2020-12-28T20:49:02', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '19efdef7-e4d6-47a8-a844-c4ab39517658'	System	29 Dec 2020 02:49:05
User entered '28 Dec 2020 20:49:02'	System	29 Dec 2020 02:49:05

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-01-04T02:17:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd10e5bfb-5de6-4725-bffd-2bf1e056f2f5'	System	04 Jan 2021 08:17:45
User entered 'No (N)'	System	04 Jan 2021 08:17:45

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-01-04T02:17:38', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd10e5bfb-5de6-4725-bffd-2bfl e056f2f5'	System	04 Jan 2021 08:17:45
User entered 'No (N)'	System	04 Jan 2021 08:17:45

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-01-04T02:17:40', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'd10e5bfb-5de6-4725-bffd-2bfl e056f2f5'	System	04 Jan 2021 08:17:45
User entered '04 Jan 2021 02:17:40'	System	04 Jan 2021 08:17:45

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-01-11T06:05:35', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '06685f39-dbe3-410d-a6e9-f7991abd0a31'	System	11 Jan 2021 12:05:42
User entered 'No (N)'	System	11 Jan 2021 12:05:42

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-01-11T06:05:37', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '06685f39-dbe3-410d-a6e9-f7991abd0a31'	System	11 Jan 2021 12:05:42
User entered 'No (N)'	System	11 Jan 2021 12:05:42

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-01-11T06:05:39', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '06685f39-dbe3-410d-a6e9-f7991abd0a31' User entered '11 Jan 2021 06:05:39'	System	11 Jan 2021 12:05:42
	System	11 Jan 2021 12:05:42

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-01-18T05:15:14', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '179c6666-ff24-45e9-b51f-af9920aecdl1a'	System	18 Jan 2021 11:15:25
User entered 'No (N)'	System	18 Jan 2021 11:15:25

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-01-18T05:15:17', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '179c6666-ff24-45e9-b51f-af9920aecdl1a'	System	18 Jan 2021 11:15:25
User entered 'No (N)'	System	18 Jan 2021 11:15:25

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-01-18T05:15:19', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '179c6666-ff24-45e9-b51f-af9920aecdl1a'	System	18 Jan 2021 11:15:25
User entered '18 Jan 2021 05:15:19'	System	18 Jan 2021 11:15:25

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-01-28T13:36:18', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '0db4909c-fa5b-4f54-985f-a338b16c6af4'	System	28 Jan 2021 19:36:24
User entered 'No (N)'	System	28 Jan 2021 19:36:24

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-01-28T13:36:20', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '0db4909c-fa5b-4f54-985f-a338b16c6af4'	System	28 Jan 2021 19:36:24
User entered 'No (N)'	System	28 Jan 2021 19:36:24

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-01-28T13:36:22', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '0db4909c-fa5b-4f54-985f-a338b16c6af4'	System	28 Jan 2021 19:36:24
User entered '28 Jan 2021 13:36:22'	System	28 Jan 2021 19:36:24

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-02-01T09:10:23', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '98ef18be-5603-49d5-b770-9fff59d04a77'	System	01 Feb 2021 15:10:30
User entered 'No (N)'	System	01 Feb 2021 15:10:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-02-01T09:10:25', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '98ef18be-5603-49d5-b770-9fff59d04a77'	System	01 Feb 2021 15:10:30
User entered 'No (N)'	System	01 Feb 2021 15:10:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-02-01T09:10:27', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '98ef18be-5603-49d5-b770-9fff59d04a77'	System	01 Feb 2021 15:10:30
User entered '01 Feb 2021 09:10:27'	System	01 Feb 2021 15:10:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-02-08T08:13:43', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c9059be-74f9-44bc-bea9-ff34eb81a183'	System	08 Feb 2021 14:13:53
User entered 'No (N)'	System	08 Feb 2021 14:13:53

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-02-08T08:13:47', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c9059be-74f9-44bc-bea9-ff34eb81a183'	System	08 Feb 2021 14:13:53
User entered 'No (N)'	System	08 Feb 2021 14:13:53

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-02-08T08:13:51', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '7c9059be-74f9-44bc-bea9-ff34eb81a183'	System	08 Feb 2021 14:13:53
User entered '08 Feb 2021 08:13:51'	System	08 Feb 2021 14:13:53

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-02-15T06:57:45', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ec007492-5443-4fae-8ffc-8c18013e6c69'	System	15 Feb 2021 12:57:58
User entered 'No (N)'	System	15 Feb 2021 12:57:58

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-02-15T06:57:48', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ec007492-5443-4fae-8ffc-8c18013e6c69'	System	15 Feb 2021 12:57:58
User entered 'No (N)'	System	15 Feb 2021 12:57:58

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-02-15T06:57:50', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ec007492-5443-4fae-8ffc-8c18013e6c69'	System	15 Feb 2021 12:57:58
User entered '15 Feb 2021 06:57:50'	System	15 Feb 2021 12:57:58

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-02-24T06:58:24-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1343cc61-a59b-479f-b5d6-ef8bde8d7755'	System	24 Feb 2021 12:58:33
User entered 'No (N)'	System	24 Feb 2021 12:58:33

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-02-24T06:58:27-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1343cc61-a59b-479f-b5d6-ef8bde8d7755'	System	24 Feb 2021 12:58:33
User entered 'No (N)'	System	24 Feb 2021 12:58:33

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-02-24T06:58:29-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1343cc61-a59b-479f-b5d6-ef8bde8d7755'	System	24 Feb 2021 12:58:33
User entered '24 Feb 2021 06:58:29'	System	24 Feb 2021 12:58:33

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-03-01T08:42:42-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '03505296-26bf-4e8e-aef3-abb3afe8179c'	System	01 Mar 2021 14:42:50
User entered 'No (N)'	System	01 Mar 2021 14:42:50

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-03-01T08:42:45-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '03505296-26bf-4e8e-aef3-abb3afe8179c'	System	01 Mar 2021 14:42:50
User entered 'No (N)'	System	01 Mar 2021 14:42:50

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-01T08:42:48-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '03505296-26bf-4e8e-aef3-abb3afe8179c'	System	01 Mar 2021 14:42:50
User entered '01 Mar 2021 08:42:48'	System	01 Mar 2021 14:42:50

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-03-08T11:38:17-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dcb13916-d291-4900-a0c0-f658f57df50f'	System	08 Mar 2021 17:38:23
User entered 'No (N)'	System	08 Mar 2021 17:38:23

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-03-08T11:38:19-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dcb13916-d291-4900-a0c0-f658f57df50f'	System	08 Mar 2021 17:38:23
User entered 'No (N)'	System	08 Mar 2021 17:38:23

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-08T11:38:21-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'dcb13916-d291-4900-a0c0-f658f57df50f'	System	08 Mar 2021 17:38:23
User entered '08 Mar 2021 11:38:21'	System	08 Mar 2021 17:38:23

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-03-15T09:10:28-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6e16147b-6e22-4ef8-8ddb-047d580099d2'	System	15 Mar 2021 14:10:38
User entered 'No (N)'	System	15 Mar 2021 14:10:38

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-03-15T09:10:32-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6e16147b-6e22-4ef8-8ddb-047d580099d2'	System	15 Mar 2021 14:10:38
User entered 'No (N)'	System	15 Mar 2021 14:10:38

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-15T09:10:34-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '6e16147b-6e22-4ef8-8ddb-047d580099d2'	System	15 Mar 2021 14:10:38
User entered '15 Mar 2021 09:10:34'	System	15 Mar 2021 14:10:38

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-03-22T06:52:19-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ee57b00e-5e2a-4feb-bb3c-d41d53f28843'	System	22 Mar 2021 11:52:31
User entered 'No (N)'	System	22 Mar 2021 11:52:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-03-22T06:52:24-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ee57b00e-5e2a-4feb-bb3c-d41d53f28843'	System	22 Mar 2021 11:52:31
User entered 'No (N)'	System	22 Mar 2021 11:52:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-22T06:52:26-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'ee57b00e-5e2a-4feb-bb3c-d41d53f28843'	System	22 Mar 2021 11:52:31
User entered '22 Mar 2021 06:52:26'	System	22 Mar 2021 11:52:31

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-03-30T10:23:48-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa' User entered 'Yes (Y)'	System	30 Mar 2021 15:24:29
	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-03-30T10:23:53-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa'	System	30 Mar 2021 15:24:29
User entered 'No (N)'	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-30T10:23:59-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa'	System	30 Mar 2021 15:24:29
User entered 'No (N)'	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-30T10:24:07-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa' User entered 'Yes (Y)'	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-30T10:24:13-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa'	System	30 Mar 2021 15:24:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-30T10:24:17-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '25a70ff1-1bf1-426e-b41e-39ff017b26fa' User entered '30 Mar 2021 10:24:17'	System	30 Mar 2021 15:24:29

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-04-05T07:58:16-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e6baa9b3-fdb6-4b68-a179-dc67ed2a3d1f'	System	05 Apr 2021 12:58:27
User entered 'No (N)'	System	05 Apr 2021 12:58:27

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-04-05T07:58:19-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e6baa9b3-fdb6-4b68-a179-dc67ed2a3d1f'	System	05 Apr 2021 12:58:27
User entered 'No (N)'	System	05 Apr 2021 12:58:27

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-04-05T07:58:21-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e6baa9b3-fdb6-4b68-a179-dc67ed2a3d1f'	System	05 Apr 2021 12:58:27
User entered '05 Apr 2021 07:58:21'	System	05 Apr 2021 12:58:27

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-04-13T10:18:11-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'a8b98dce-bfeb-45d2-9ff0-30c903f92075'	System	13 Apr 2021 15:18:19
User entered 'No (N)'	System	13 Apr 2021 15:18:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-04-13T10:18:13-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'a8b98dce-bfeb-45d2-9ff0-30c903f92075'	System	13 Apr 2021 15:18:19
User entered 'No (N)'	System	13 Apr 2021 15:18:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-04-13T10:18:15-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'a8b98dce-bfeb-45d2-9ff0-30c903f92075'	System	13 Apr 2021 15:18:19
User entered '13 Apr 2021 10:18:15'	System	13 Apr 2021 15:18:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-04-19T10:06:37-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'aacd3f9f-da94-4dd6-b6f6-206479025a5c'	System	19 Apr 2021 15:06:46
User entered 'No (N)'	System	19 Apr 2021 15:06:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-04-19T10:06:39-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'aacd3f9f-da94-4dd6-b6f6-206479025a5c'	System	19 Apr 2021 15:06:46
User entered 'No (N)'	System	19 Apr 2021 15:06:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-04-19T10:06:41-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'aacd3f9f-da94-4dd6-b6f6-206479025a5c' User entered '19 Apr 2021 10:06:41'	System	19 Apr 2021 15:06:46
	System	19 Apr 2021 15:06:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-04-26T07:27:19-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'df608759-a48c-4667-8890-f0cadeebbd4a' User entered 'No (N)'	System	26 Apr 2021 12:27:30
	System	26 Apr 2021 12:27:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-04-26T07:27:21-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'df608759-a48c-4667-8890-f0cadeebbd4a' User entered 'No (N)'	System	26 Apr 2021 12:27:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-04-26T07:27:23-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'df608759-a48c-4667-8890-f0cadeebbd4a' User entered '26 Apr 2021 07:27:23'	System	26 Apr 2021 12:27:30
	System	26 Apr 2021 12:27:30

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[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 (e20e96e9de4da9ac)', Time: '2021-05-03T07:05:09-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1dcabcea-e6ce-4a01-b601-5d0456b58746'	System	03 May 2021 12:05:19
User entered 'No (N)'	System	03 May 2021 12:05:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Have you been exposed to someone with 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 (e20e96e9de4da9ac)', Time: '2021-05-03T07:05:12-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1dcabcea-e6ce-4a01-b601-5d0456b58746'	System	03 May 2021 12:05:19
User entered 'No (N)'	System	03 May 2021 12:05:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-05-03T07:05:14-05:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: '1dcabcea-e6ce-4a01-b601-5d0456b58746'	System	03 May 2021 12:05:19
User entered '03 May 2021 07:05:14'	System	03 May 2021 12:05:19

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:32:46

US3592061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:32:46
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:32:46

US3592061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:18:28

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 20:03:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-01T08:42:54-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e0c91195-9e89-4b78-80da-2d4ee6e96f83'	System	01 Mar 2021 14:43:05
User entered 'No (N)'	System	01 Mar 2021 14:43:05

US3592061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:18:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:03:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e20e96e9de4da9ac)', Time: '2021-03-01T08:43:01-06:00', User OID: 'PatientReportedOutcome (US3592061)', ODM File OID: 'e0c91195-9e89-4b78-80da-2d4ee6e96f83'	System	01 Mar 2021 14:43:05
User entered '01 Mar 2021 08:43:01'	System	01 Mar 2021 14:43:05

US3592061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:35

US3592061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:43
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 16:45:35

US3592061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 16:45:35

US3592061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:43
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:35

US3592061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:43:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:04:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:38

US3592061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 08:12:56
User entered 'l'	System	30 Oct 2020 16:45:38

US3592061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 18:32:19

US3592061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:52
User entered '3 Dec 2020'	(b) (4), (b) (6)	05 Dec 2020 18:32:19

US3592061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Dec 2020 18:32:19

US3592061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:52
User entered empty.	(b) (4), (b) (6)	05 Dec 2020 18:32:19

US3592061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:29:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Dec 2020 18:32:27

US3592061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User entered 'I'	System	05 Dec 2020 18:32:27

US3592061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:44

US3592061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:44

US3592061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:44

US3592061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:44

US3592061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:12:49

US3592061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User entered 'l'	System	05 Jan 2021 16:12:49

US3592061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:28:46

US3592061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:28:46

US3592061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:28:46

US3592061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:28:46

US3592061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:28:53

US3592061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:43:32
User entered 'I'	System	04 Feb 2021 15:28:53

US3592061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:41:33

US3592061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:41:33

US3592061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:41:33

US3592061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered 'VISIT4'	System	09 Mar 2021 16:41:33

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered empty.	System	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered empty.	System	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered empty.	System	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered empty.	System	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered empty.	System	02 Apr 2021 18:54:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26

US3592061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26

US3592061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:43:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:43:52

US3592061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:44:30

US3592061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:44:30

US3592061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14:30'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:44:30

US3592061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered '8 Mar 2021 14:30'	System	09 Mar 2021 16:44:30

US3592061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:48:20

US3592061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:08:26
User entered 'I'	System	09 Mar 2021 16:48:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:28

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:07
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:28

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:07
User entered '11:07'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:28

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:13
User entered '13 Nov 2020 11:07'	System	14 Nov 2020 00:35:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:28

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:07
User entered 'Safety Call (Safety Call)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:28

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:13
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:07
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 1 (Day 1)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '11 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:37:27

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 2 (Day 2)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '12 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered missing code ND - Not Done.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:38:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 3 (Day 3)'	(b) (4) Diandra Henriques (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:30:41
User entered '0'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '97'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered '36.6' C	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Moderate (Moderate)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'Mild (Mild)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:30:41
User entered 'None (None)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:12

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:56:05

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '97'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 15:57:22

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '95'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 16:12:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:30

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:08

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:17:52

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '96'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User entered '%'	System	22 Feb 2021 16:19:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:28

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:19:20

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 16:14:02
DataPoint Un-verified.	(b) (4), (b) (6)	05 Jan 2021 16:14:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 16:14:02
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:31:02
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 00:40:33
User entered empty.	Diandra Henriques (b) (4)	14 Nov 2020 00:40:33
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered 'No (N)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:02
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:40:33

US3592061

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:28

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:14:30
User entered '0'	System	05 Jan 2021 16:14:02

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:18:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:43:22
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Subject used incorrect tube, confirming this date for this sample. Will reconcile with PPD Central Lab.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:33:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is recorded under Illness Visit Day 3 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:49:13
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:10:26
User entered '15 Nov 2020'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:18:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:43:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Subject used incorrect tube, confirming this date for this samples. Will reconcile with PPD Central Lab' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:39:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 5 in EDC, however the same is reported under COVID PCR Saliva Day 3 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:49:32
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:10:26
User entered '17 Nov 2020'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:18:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:24:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 07:07:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Will reconcile with PPD Central Lab - DCR sent 15 APR 2021' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	15 Apr 2021 21:34:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 9 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 10:44:45
Signature has been broken.	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:40:54
User entered '19 Nov 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:40:54
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:44:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:24:25

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Sample entered' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 16:24:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:52:41
User entered '19 Nov 2020'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:18:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:23:49
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 22:17:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 07:08:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Will reconcile with PPD Central Lab - DCR sent 15 APR 2021' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	15 Apr 2021 21:34:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020 is recorded under Illness visit day 7 in EDC, however the same is reported under Illness visit day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 10:45:11
Signature has been broken.	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:40:54
User entered '21 Nov 2020' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	10 Apr 2021 14:40:54
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:10:26
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:23:49
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:18:28

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Signature has been broken.	(b) (4)	
	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
User signature succeeded.	(b) (4)	
	Terry Poling (b) (4)	25 Mar 2021 20:10:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 22:17:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:18:28

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Signature has been broken.	(b) (4)	
	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
	(b) (4)	
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:24:45
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 22:17:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Signature has been broken.	(b) (4)	
	Diandra Henriques (b) (4)	10 Apr 2021 14:41:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	Diandra Henriques (b) (4)	10 Apr 2021 14:41:05
	(b) (4)	
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
	(b) (4)	
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:24:45
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:18:28

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:18:28

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Signature has been broken.	(b) (4)	
	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4)	
reason for change: Data Entry Error	Diandra Henriques (b) (4)	10 Apr 2021 14:40:54
User signature succeeded.	(b) (4)	
	Terry Poling (b) (4)	25 Mar 2021 20:10:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 22:17:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 22:17:50
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 22:17:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 22:17:43

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:17:43

US3592061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:14
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 05:10:12
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 22:18:02
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:31:23
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 07:26:42
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:25:11
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '13 Nov 2020'	(b) (4) Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:25:12
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:14
User entered 'SICKD1'	System	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '15:10'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User entered '13 Nov 2020 15:10'	System	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '170.0' cm	Diandra Henriques (b) (4)	14 Nov 2020 00:35:04
DataPoint set to visible.	(b) (4) System	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '108.8' kg	Diandra Henriques (b) (4)	14 Nov 2020 00:35:04
DataPoint set to visible.	(b) (4) System	14 Nov 2020 00:33:17

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '36.6' C	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered 'Oral (Oral)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered empty.	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '81'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User entered 'bpm'	System	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '16'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User entered 'breaths/min'	System	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '134'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User entered 'mmHg'	System	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:38
User entered '92'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21
User entered 'mmHg'	System	14 Nov 2020 00:35:04

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21

US3592061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:21

US3592061

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:43
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:15

US3592061

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:43
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:15

US3592061

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:18:28

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:50
User entered 'Yes (Y)'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:28

US3592061

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:18:28

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:33
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:31:50
User entered '13 Nov 2020'	Diandra Henriques (b) (4) (b) (4)	14 Nov 2020 00:35:28

US3592061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:58:29

US3592061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:58:29

US3592061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[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 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:58:29

US3592061

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 20:58:29

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Data hard locked.	(b) (4) (D) (4), (D) (6)	28 Apr 2021 06:11:32
User entered '0'	(D) (4), (b) (6)	09 Apr 2021 13:36:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:28:21

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 06:11:32
User closed query ' Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:42:10
Query ' Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:36:38
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:36:34
User opened query ' Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:57:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:28:21

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 01:32:10
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 01:32:10
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'I'	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:18:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'I'	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '107.6' kg	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	13 Jan 2021 21:01:31
DataPoint set to visible.	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '107.6' kg	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	13 Jan 2021 21:01:31
DataPoint set to visible.	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '13:34'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '12 Jan 2021 13:34'	System	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '36.8' C	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '87'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'bpm'	System	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'breaths/min'	System	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '130'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '93'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '107.6' kg	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:01:31

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	13 Jan 2021 21:01:31
DataPoint set to visible.	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14:42'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '12 Jan 2021 14:42'	System	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	13 Jan 2021 21:02:18
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	13 Jan 2021 21:02:18
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 21:02:18
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Jan 2021 21:02:09
User entered '98.8' C	(b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '75'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'bpm'	System	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'breaths/min'	System	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '123'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '83'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mmHg'	System	13 Jan 2021 21:02:09

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:02:48

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:02:48

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Urine (URINE)'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (D) (4), (D) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered empty.	System	13 Jan 2021 21:03:18

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'mRNA-1273'	System	13 Jan 2021 20:59:41
DataPoint set to visible.	System	13 Jan 2021 20:59:00

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14:09'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '12 Jan 2021 14:09'	System	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'ONCE'	System	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 20:59:41

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 23:01:01

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 23:01:01

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '13:43'	(b) (4) (D) (4), (D) (6)	18 Jan 2021 23:01:01

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '12 Jan 2021 13:43'	System	18 Jan 2021 23:01:01

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 23:01:10

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 23:01:10

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '13:40'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 23:01:10

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered '12 Jan 2021 13:40'	System	18 Jan 2021 23:01:10

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	18 Jan 2021 23:01:20

US3592061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:11:32
User entered 'l'	System	18 Jan 2021 23:01:20

US3592061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:49:38

US3592061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:49:38

US3592061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:49:38

US3592061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:49:38

US3592061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:50:09

US3592061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'l'	System	26 Jan 2021 14:50:09

US3592061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'I'	System	26 Jan 2021 14:50:09
DataPoint set to visible.	System	26 Jan 2021 14:50:09

US3592061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:45:51

US3592061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:45:51

US3592061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:45:51

US3592061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'OLD29'	System	11 Feb 2021 19:45:51

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10:25'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered '10 Feb 2021 10:25'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '71'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'bpm'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'breaths/min'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '125'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '87'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '11:32'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered '10 Feb 2021 11:32'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'bpm'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'breaths/min'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '132'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '90'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	11 Feb 2021 19:47:41

US3592061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:00

US3592061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:00

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:18:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered empty.	System	11 Feb 2021 19:48:42

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

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 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mRNA-1273'	System	11 Feb 2021 19:49:06
DataPoint set to visible.	System	26 Jan 2021 14:50:09

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '11:00'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered '10 Feb 2021 11:00'	System	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'ONCE'	System	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 19:49:06

US3592061

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:49:24

US3592061

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'l'	System	11 Feb 2021 19:49:24

US3592061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:56:53

US3592061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:56:53

US3592061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:56:53

US3592061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:56:53

US3592061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:58:11

US3592061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'l'	System	19 Feb 2021 19:58:11

US3592061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:48:34

US3592061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:48:34

US3592061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:48:34

US3592061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'OLD57'	System	09 Mar 2021 16:48:34

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14:11'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered '8 Mar 2021 14:11'	System	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '64'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'bpm'	System	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'breaths/min'	System	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '132'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '89'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered 'mmHg'	System	09 Mar 2021 16:50:39

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47

US3592061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47

US3592061

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:53

US3592061

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:50:53

US3592061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:51:16

US3592061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:51:16

US3592061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14:30'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:51:16

US3592061

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:47
User entered '8 Mar 2021 14:30'	System	09 Mar 2021 16:51:16

US3592061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:19:39
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 05:55:01
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 09:29:26
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'AE page updated added headache ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:42:29

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:28

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Per progress note written from contact with subject, she marked that response due to getting a flu vaccine - documented in conmeds' (Site from DM). User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary "Headache" lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	Diandra Henriques (b) (4) (b) (4)	20 Apr 2021 18:35:57
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 18:21:42
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 19:31:14
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 15:39:13
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 15:39:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:39:13
User signature succeeded.	Terry Poling (b) (4) (b) (4)	25 Mar 2021 20:10:26

US3592061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Day 106 and 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:41:32
Query 'Per DM CLR: Per Day 106 and 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'not an AE e-dairy response was addressed in progress note is source. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 17:28:34
User opened query 'Per DM CLR: Per Day 106 and 110, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:53:54
Query 'Per DM CLR: Per Day 106, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:53:40

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Day 106, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 09:51:02
	(b) (4), (b) (6)	30 Oct 2020 21:05:11
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:53:58
User entered 'USA-US103-2021-mRNA-1273-P301000007'	System	01 Apr 2021 16:53:37
User entered 'New'	(b) (4), (b) (6)	01 Apr 2021 16:53:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User coded data point as SOC: Psychiatric disorders, HLT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicidal ideation, LLT: Suicidal ideation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Mar 2021 15:54:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 15:54:15
Data point term sent to Coder	System	31 Mar 2021 15:51:58
User entered 'suicidal ideations'	(b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please re-confirm the hospital discharge date. As per the narrative, 2 different discharge dates are mentioned 28 May 2021 and 28 Mar 2021. Kindly reconcile and update accurately.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 14:08:26
Query 'PV Query: Please re-confirm the hospital discharge date. As per the narrative, 2 different discharge dates are mentioned 28 May 2021 and 28 Mar 2021. Kindly reconcile and update accurately.'	Diandra Henriques (b) (4)	26 Apr 2021 20:26:21
answered with 'Correct date is 28 MAR 2021, narrative has been corrected.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please re-confirm the hospital discharge date. As per the narrative, 2 different discharge dates are mentioned 28 May 2021 and 28 Mar 2021. Kindly reconcile and update accurately.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 11:44:38
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Query response noted. However please update the data when available, until then please keep this query in open status.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 11:42:49
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
Query 'Per CDM: Query response noted. However please update the data when available, until then please keep this query in open status.' answered with 'done' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:12:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:10:14
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 08:38:54
User opened query 'Per CDM: Query response noted. However please update the data when available, until then please keep this query in open status.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 08:38:52
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Unknow until medical records have been received ' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 15:52:00
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	31 Mar 2021 15:51:31
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

None

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Signature has been broken.	(b) (4) Diandra Henriques (b) (4)	26 Apr 2021 20:25:41

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT RESPONDED TO WEEKLY DIARY PROMPT INDICATION HAVING HAD CONTACT WITH A HEALTHCARE PROVIDER SINCE LAST CONTACT WITH SITE. RESEARCH ASSISTANT CALLED SUBJECT TO OBTAIN DETAILS AT WHICH TIME SUBJECT REPORTED THAT SHE VISIT THE ER AT ASCENSION ST. JOSEPH ON 25MAR2021 AND WAS ADMITTED AT THE TIME FOR SUICIDAL IDEATIONS. SHE WAS RELEASED ON 28MAY2021 WITH NEW MEDICATION FOR ANXIETY AND WAS SET UP FOR OUTPATIENT THERAPY SEEN FOR FIRST THERAPY YESTERDAY. SUBJECT HAS A HISTORY OF PSYCHIATRIC DISORDERS (ANXIETY, DEPRESSION, INSOMNIA, ATTENTION DEFICIT HYPERACTIVITY DISORDER) WILL ASK SUBJECT FOR PERMISSION TO OBTAIN RECORDS, WILL UPDATED SAE ONCE RECORDS ARE AVAILABLE. FOLLOWUP OF RECORDS RECEIVED AND REVIEWED. SUBJECT VOLUNTARILY TOOK HERSELF TO THE EMERGENCY ROOM TO SEEK HELP AFTER SHE WAS EXPERIENCING OVERWHELMING GRIEF AND FEELING (b) (6) (b) (6) SHE WAS HAVING THOUGHTS OF SUICIDE AND WISHING TO BE DEAD FOR TWO WEEKS PRIOR. SHE DID REPORT A PLAN AND INTENT FOR SUICIDE WHILE OUT OF THE HOSPITAL BUT ONLY SUICIDAL THOUGHTS ONCE ADMITTED. URINE DRUG SCREEN ON ADMISSION WAS ONLY POSITIVE FOR AMPHETAMINES, (SHE IS PRESCRIBED VYVANSE). SUBJECT'S GRIEF AND STRESS PRIMARILY RELATED TO DEATH OF (b) (6) DURING HOSPITALIZATION, SHE ATTENDED GROUP THERAPY SESSIONS, INDIVIDUAL THERAPY SESSIONS, AND IMPROVED BASELINE	Diandra Henriques (b) (4) (b) (4)	26 Apr 2021 20:25:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
ANXIETY AND DEPRESSION. SHE WAS STARTED ON BUSPIRONE AND HYDROXYZINE AND DISCHARGED ON THESE MEDICATIONS. HER HOME MEDICATIONS SHE WAS TAKING FOR HER PREVIOUSLY DIAGNOSED PSYCHIATRIC CONDITIONS WERE CONTINUED DURING THE COURSE OF HER STAY AND UPON DISCHARGE. SHE WAS DISCHARGED 28MAR2021 TO HOME WITH HUSBAND AND FOLLOWUP APPOINTMENTS SCHEDULED FOR OUTPATIENT INDIVIDUAL AND COUPLE'S THERAPY. RELEVANT MEDICAL HISTORY OF ANXIETY, DEPRESSION, INSOMNIA AND ATTENTION DEFICIT HYPERACTIVITY DISORDER.' reason for change: Data Entry Error		
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 21:07:47
User closed query 'PV Query: Please update narrative as it says subject was discharged on 28 May 2021. ' (Site from Safety).		19 Apr 2021 21:07:35
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		19 Apr 2021 21:07:24
User closed query 'PV: Please provide details of new medication given for anxiety. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 21:07:11
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
Query 'PV: Please provide details of new medication given for anxiety. ' answered with 'done' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:16:07
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:40:50

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:40:46

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT RESPONDED TO WEEKLY DIARY PROMPT INDICATION HAVING HAD CONTACT WITH A HEALTHCARE PROVIDER SINCE LAST CONTACT WITH SITE. RESEARCH ASSISTANT CALLED SUBJECT TO OBTAIN DETAILS AT WHICH TIME SUBJECT REPORTED THAT SHE VISIT THE ER AT ASCENSION ST. JOSEPH ON 25MAR2021 AND WAS ADMITTED AT THE TIME FOR SUICIDAL IDEATIONS. SHE WAS RELEASED ON 28MAY2021 WITH NEW MEDICATION FOR ANXIETY AND WAS SET UP FOR OUTPATIENT THERAPY SEEN FOR FIRST THERAPY YESTERDAY. SUBJECT HAS A HISTORY OF PSYCHIATRIC DISORDERS (ANXIETY, DEPRESSION, INSOMNIA, ATTENTION DEFICIT HYPERACTIVITY DISORDER) WILL ASK SUBJECT FOR PERMISSION TO OBTAIN RECORDS, WILL UPDATED SAE ONCE RECORDS ARE AVAILABLE. Followup of records received and reviewed. Subject voluntarily took herself to the emergency room to seek help after she was experiencing overwhelming grief and feeling (b) (6) (b) (6) She was having thoughts of suicide and wishing to be dead for two weeks prior. She did report a plan and intent for suicide while out of the hospital but only suicidal thoughts once admitted. Urine drug screen on admission was only positive for amphetamines, (she is prescribed Vyvanse). Subject's grief and stress primarily related to (b) (6) (b) (6) During hospitalization, she attended group therapy sessions, individual therapy sessions, and improved baseline anxiety and depression. She was started on Buspirone and Hydroxyzine and discharged on these medications. Her home medications she was taking for her previously diagnosed psychiatric conditions were continued during the course of her stay and upon discharge. She was discharged 28May2021 to home with husband	(b) (4), (b) (6)	16 Apr 2021 14:40:34

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
and followup appointments scheduled for outpatient individual and couple's therapy. Relevant medical history of anxiety, depression, insomnia and attention deficit hyperactivity disorder.' reason for change: Data Entry Error		
Query 'PV Query: Please update narrative as it says subject was discharged on 28 May 2021. ' answered with 'Confirm this is correct. Subject was discharged on 28May2021.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:13:03
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:39:07
User opened query 'PV Query: Please update narrative as it says subject was discharged on 28 May 2021. ' (Site from Safety).		09 Apr 2021 16:38:54
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		09 Apr 2021 16:38:40
User opened query 'PV: Please provide details of new medication given for anxiety. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 16:38:20
User entered 'Subject responded to weekly diary prompt indication having had contact with a healthcare provider since last contact with site. Research assistant called subject to obtain details at which time subject reported that she visit the ER at Ascension St. Joseph on 25MAR2021 and was admitted at the time for suicidal ideations. She was released on 28MAY2021 with new medication for anxiety and was set up for outpatient therapy seen for first therapy yesterday. Subject has a history of psychiatric disorders (anxiety, depression, insomnia, attention deficit hyperactivity disorder) will ask subject for permission to obtain records, will updated SAE once records are available.'	(b) (4), (b) (6)	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 15:51:31

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:45:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:45:35
Data point term sent to Coder	System	20 Apr 2021 19:44:33
User entered 'headache'	(b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 20:28:01
User entered '13 Aug 2020' reason for change: Data Entry Error	System	20 Apr 2021 20:28:01
User opened query 'Future date has been entered. Please correct.' (Site from System).	Diandra Henriques (b) (4)	20 Apr 2021 20:28:01
User entered '13 Aug 2021'	(b) (4)	20 Apr 2021 19:44:10
	(b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User entered empty.	System	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '16 Aug 2020' reason for change: Data Entry Error	System	20 Apr 2021 20:28:01
User opened query 'Future date has been entered. Please correct.' (Site from System).	Diandra Henriques (b) (4)	20 Apr 2021 20:28:01
User entered '16 Aug 2021'	(b) (4)	
	System	20 Apr 2021 19:44:10
	(b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User entered empty.	System	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'l'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User entered '0'	System	20 Apr 2021 19:44:10

US3592061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50
User entered '0'	System	20 Apr 2021 19:44:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 19:46:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Apr 2021 19:46:34
Data point term sent to Coder	System	20 Apr 2021 19:45:33
User entered 'nausea'	(b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User entered empty.	System	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 19:45:07
User entered '15 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:45:07
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	20 Apr 2021 19:44:54
User entered '15 Apr 2020'	(b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User entered empty.	System	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'l'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User entered '0'	System	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52
User entered '0'	System	20 Apr 2021 19:44:54

US3592061

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 02:16:52

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:28

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:19:39
User closed query 'Please enter con-meds associated with SAE. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:01:38
Query 'Please enter con-meds associated with SAE. ' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:19:47
User opened query 'Please enter con-meds associated with SAE. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:23:12
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 06:31:40
Query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Dairy NA when call completed however subject report corresponds with entries on Conmed page. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:48:55
User opened query 'Per DM CLR: Per Diary Dose 1 Day 7, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:07:32
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 21:05:22

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:39:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:16:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:16:10
Data point term sent to Coder	System	09 Aug 2020 20:43:15
User entered 'Mirena'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Contraception'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '52'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'other (OTHER)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'every three years'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'intra-uterine'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:17:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:42:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:42:45
User entered '01 Jan 2018'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 20:42:45

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:45:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:45:41
Data point term sent to Coder User entered 'Vyvanse'	System (b) (4), (b) (6)	09 Aug 2020 20:44:15 09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Attention deficit hyperactivity disorder'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '60'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 04:26:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:43:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:43:50
User entered '01 Jan 2016'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:43:50

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:46:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:46:42
Data point term sent to Coder User entered 'Ambien'	System (b) (4), (b) (6)	09 Aug 2020 20:45:16 09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:27
User entered 'Insomnia'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:29
User entered '5'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:31
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:32
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:36
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:40
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2005). Update if appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 03:44:28
Query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2005). Update if appropriate. Otherwise, provide clarification. ' answered with 'medication is not' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:14:39
User opened query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2005). Update if appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:43:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 09:21:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:17:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:44:43
User entered '01 Jan 2005'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:46
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:52
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:53
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:44:37

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:47:42
Data point term sent to Coder	System	09 Aug 2020 20:46:16
User entered 'Omega 3'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'nutritional supplement'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '520'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:17:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:45:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:45:23
User entered '01 Jan 2018'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:45:23

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DESVENLAFAXINE SUCCINATE, PRODUCTSYNONYM: PRISTIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:47:42
Data point term sent to Coder User entered 'Pristiq'	System (b) (4), (b) (6)	09 Aug 2020 20:46:17 09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Depression'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '100'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:17:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:46:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:46:06
User entered '01 Jan 2018'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:46:06

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:51:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:51:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:20
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 Aug 2020 23:32:20
Data point term sent to Coder User entered 'B12'	System (b) (4), (b) (6)	09 Aug 2020 20:49:18 09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'nutritional supplement'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '5000'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'ug (ug)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Other (OTHER)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'sublingual'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:17:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:48:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:48:34
User entered '01 Jan 2018'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:48:34

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:51:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:51:34
Data point term sent to Coder User entered 'Zyrtec'	System (b) (4), (b) (6)	09 Aug 2020 20:50:19 09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	27 Oct 2020 14:44:49
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:50
User entered 'Seasonal allergies'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:53
User entered '10'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:54
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:56
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:44:59
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:45:01
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:45:04
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2018). Update if appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 03:44:45
Query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2018). Update if appropriate. Otherwise, provide clarification. ' answered with 'Medication is not' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	20 Jan 2021 22:12:59 27 Oct 2020 14:45:07
User opened query 'Per DM CLR: Please review and confirm that this medication is not given prior to MH condition (UN UNK 2018). Update if appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:22:20
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:18:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:49:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:49:24
User entered '01 Jan 2018'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:45:12
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:45:16
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	27 Oct 2020 14:45:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:49:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DOXEPIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:51:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 20:51:34
Data point term sent to Coder	System	09 Aug 2020 20:50:19
User entered 'Doxepin'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Insomnia'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '10'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 02:18:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	09 Aug 2020 20:50:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	09 Aug 2020 20:50:09
User entered '01 Jul 2020'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 20:50:09

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:34
Data point term sent to Coder	System	25 Aug 2020 15:15:21
User entered 'Tylenol'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:37
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:32:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:48:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:18:07

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:22:05
User entered 'headache'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:43
User entered '500'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:45
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:48
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	26 Aug 2020 20:44:23
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	26 Aug 2020 20:44:23
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	26 Aug 2020 20:39:43
User entered 'once (ONCE)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:50
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:53
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:55
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 20:44:23
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:48:58
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:49:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 20:39:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:49:02
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 20:39:43
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:49:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User entered empty.	System	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User entered empty.	System	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:28
User entered empty.	System	25 Aug 2020 15:15:04

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:13:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:13:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 23:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 23:17:38
Data point term sent to Coder User entered 'Probiotic'	System (b) (4), (b) (6)	25 Aug 2020 23:16:46 25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'nutritional supplement'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '01 Jan 2018'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 23:16:13

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:52:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:52:43
Data point term sent to Coder	System	14 Sep 2020 16:51:58
User entered 'tylenol'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'headache'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '1500'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '5 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '5 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:20:19
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Confirm does not meeting AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:17:01

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 03:36:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User entered '2'	System	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User entered 'I'	System	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:36
User entered '804 (804)'	System	14 Sep 2020 16:51:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 16:54:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 16:54:41
Data point term sent to Coder	System	14 Sep 2020 16:54:04
User entered 'advil'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 08:39:04
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:17:00
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:33:27

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:08:56
User entered 'headache'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '600'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 15:27:51
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 16:53:55
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:53:55
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 16:53:42
User entered '15 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 15:27:51
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 16:53:55
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 16:53:55
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	14 Sep 2020 16:53:42
User entered '15 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:20:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Confirm does not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:17:19

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 03:36:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:40
User entered empty.	System	14 Sep 2020 16:53:42

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: TERBINAFINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:57:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:57:37
Data point term sent to Coder	System	30 Sep 2020 15:30:24
User entered 'terbinifate'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ECZEMA GENERALIZED should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 11:08:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ECZEMA GENERALIZED should be recorded, and update con med indication or provide clarification. ' answered with 'not a worsening ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:17:12
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 18:33:27
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ECZEMA GENERALIZED should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:09:17
User entered 'Eczema generalized'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '250'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '16 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 15:29:41

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:05:32
Data point term sent to Coder	System	26 Oct 2020 17:21:21
User entered 'tylenol'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 06:48:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:17:18

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 04:53:56
	(b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'headache'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '1500'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '13 Aug 2020'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered '13 Aug 2020'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 18:33:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User entered 'I'	System	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User entered 'I'	System	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:48
User entered '804 (804)'	System	26 Oct 2020 17:20:40

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO-BISMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 16:19:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 16:19:28
Data point term sent to Coder	System	05 Jan 2021 16:18:52
User entered 'pepto-bismol'	(b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 06:32:17
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	17 Feb 2021 17:44:28
' answered with 'not an AE ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	05 Feb 2021 06:51:52
' (Site from DM).		
User entered 'diarrhea'	(b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '30'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered empty.	System	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered empty.	System	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered empty.	System	05 Jan 2021 16:18:35

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 16:20:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 16:20:30
Data point term sent to Coder	System	05 Jan 2021 16:19:54
User entered 'tylenol extra strength'	(b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 06:32:27
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	17 Feb 2021 17:44:37
' answered with 'not an AE ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.	(b) (4), (b) (6)	05 Feb 2021 06:52:02
' (Site from DM).		
User entered 'headache'	(b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '1500'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered empty.	System	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered empty.	System	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:57
User entered empty.	System	05 Jan 2021 16:19:24

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 16:21:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 16:21:29
Data point term sent to Coder	System	05 Jan 2021 16:20:54
User entered 'influenza vaccine'	(b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:55
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0.5'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User entered empty.	System	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User entered empty.	System	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:03
User entered empty.	System	05 Jan 2021 16:20:31

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE HYDROCHLORIDE, PRODUCTSYNONYM: BUSPAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 14:57:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 14:57:48
Data point term sent to Coder	System	16 Apr 2021 14:56:26
User entered 'Buspar'	(b) (4), (b) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Major depressive disorder, severe, recurrent'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '10'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'mg (mg)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'twice daily (BID)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Oral (ORAL)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '25 Mar 2021'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 14:55:29

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:13:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:13:59
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
Data point term sent to Coder	System	16 Apr 2021 15:13:54
User entered 'Hydroxyzine'	(b) (4), (b) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Major depressive disorder, severe, recurrent'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '50'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'mg (mg)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'three times daily (TID)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Oral (ORAL)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '25 Mar 2021'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered '0'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'Yes (Y)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered empty.	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:45:47
User entered 'No (N)'	(b) (4) (D) (4), (D) (6)	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:18:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:13:33

US3592061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:18:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	25 Mar 2021 20:10:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 21:05:16
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 19:03:22

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:16
User entered 'USA-US103-2021-MRNA-1273-P301000007'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Terry'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Poling'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '1709 S Rock Rd'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Wichita'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'KS'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '67207'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:46:54
User entered 'US'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 14:08:47
User entered '2'	System	19 Apr 2021 13:47:07
User entered '1'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:16
User entered 'USA-US103-2021-MRNA-1273-P301000007'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Terry'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Poling'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '1709 S Rock Rd'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Wichita'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'KS'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '67207'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:46:54
User entered 'US'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 14:08:47
User entered '2'	System	19 Apr 2021 13:47:07
User entered '1'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '01/Apr/2021 12:54'	(b) (4) System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:46:54
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:16
User entered 'USA-US103-2021-MRNA-1273-P301000007'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Terry'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Poling'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '1709 S Rock Rd'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Wichita'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'KS'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '67207'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:46:54
User entered 'US'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 14:08:47
User entered '2'	System	19 Apr 2021 13:47:07
User entered '1'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '19/Apr/2021 13:47'	(b) (4) System	19 Apr 2021 13:47:07

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'I'	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:47:07

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:16
User entered 'USA-US103-2021-MRNA-1273-P301000007'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Yes (Y)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'No (N)'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Terry'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Poling'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '1709 S Rock Rd'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'Wichita'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered 'KS'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 16:54:20
User entered '67207'	System	01 Apr 2021 16:53:37

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
Reviewed for Safety.	(b) (4) (D) (4), (D) (6)	19 Apr 2021 13:46:54
User entered 'US'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Apr 2021 14:08:47
User entered '2'	System	19 Apr 2021 13:47:07
User entered '1'	System	01 Apr 2021 16:54:28

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered '27/Apr/2021 10:08'	(b) (4) System	27 Apr 2021 14:08:47

US3592061

Folder: SAE USA-US103-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:28

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 07:06:35
User entered 'I'	(b) (4) (D) (4), (D) (6)	27 Apr 2021 14:08:47