

US3202185 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:40:23

All time stamps listed in this document are displayed in GMT

US3202185

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

[Participant ID](#)

US3202185

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

US3202185

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3202185

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:10:32

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Condition	ELEVATED LIVER TESTS- CIRRHOSIS
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202185

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:19 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:19
Height (<i>xxx.x</i>)	178.5 cm
Weight (<i>xxx.x</i>)	85.6 kg
BMI (<i>xxx.x</i>)	26.86565 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104079

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:19
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

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: Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 AUG 2020

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

Treatment Date and Time (derived) 14 AUG 2020 12:00

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: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	14 AUG 2020 11:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp 14 AUG 2020 12:41

PC Open Date & Time 14 AUG 2020 12:20

PC Close Date & Time 14 AUG 2020 14:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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 96.7 °F

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

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

PC Time Stamp	14 AUG 2020 16:05
PC Open Date & Time	14 AUG 2020 15:45
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:04

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

16 AUG 2020 12:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 15:29

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

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 18 AUG 2020 13:20

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 15:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

95.6 °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

20 AUG 2020 17:44

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:42

PC Open Date & Time

14 AUG 2020 12:20

PC Close Date & Time

14 AUG 2020 14:50

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

14 AUG 2020 16:09

PC Open Date & Time

14 AUG 2020 15:45

PC Close Date & Time

15 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

15 AUG 2020 12:05

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

16 AUG 2020 12:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

17 AUG 2020 15:29

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

18 AUG 2020 13:22

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

19 AUG 2020 15:06

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

20 AUG 2020 17:45

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 12:43
PC Open Date & Time	14 AUG 2020 12:20
PC Close Date & Time	14 AUG 2020 14:50

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 16:10
PC Open Date & Time	14 AUG 2020 15:45
PC Close Date & Time	15 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:06
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:06
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 15:30
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

60 of 2116

EAB) (1725)

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 13:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:07
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 12:44:37

Generated On: 09 Jun 2021 15:40:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 10:34
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 12:44:37

Generated On: 09 Jun 2021 15:40:23

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)	14 SEP 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:58
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3202185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

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.

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 11:17 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 11:17

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

US3202185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

10:46 (24 HR)

Collection date and time (derived)

14 SEP 2020 10:46

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:43	14 SEP 2020 10:43
Nasopharyngeal Swab 2	No		

US3202185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:04

PC Open Date & Time

14 SEP 2020 11:37

PC Close Date & Time

14 SEP 2020 14:07

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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 98.2 °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	14 SEP 2020 21:19
PC Open Date & Time	14 SEP 2020 15:02
PC Close Date & Time	15 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

97.4 °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

16 SEP 2020 12:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

97.6 °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

17 SEP 2020 12:02

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

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.

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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

19 SEP 2020 04:40

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

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.

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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

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:04

PC Open Date & Time

14 SEP 2020 11:37

PC Close Date & Time

14 SEP 2020 14:07

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

14 SEP 2020 21:19

PC Open Date & Time

14 SEP 2020 15:02

PC Close Date & Time

15 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

15 SEP 2020 12:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

16 SEP 2020 12:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

17 SEP 2020 12:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 04:37

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 12:05
PC Open Date & Time	14 SEP 2020 11:37
PC Close Date & Time	14 SEP 2020 14:07

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 21:20
PC Open Date & Time	14 SEP 2020 15:02
PC Close Date & Time	15 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:05
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

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 ☒

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EAB) (1725)

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 04:40
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

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 ☒

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:03
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:32

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 10:34
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)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3202185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	12 OCT 2020 10:40

US3202185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:33

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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	15 OCT 2020 14:19:19
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 09:53:18

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 16:05:26

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 NOV 2020 09:18:40
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 07:40:21

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 15:52:08
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 13:57:12

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 11:49:45
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

22 DEC 2020 11:16:42

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

28 DEC 2020 16:24:03

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 JAN 2021 18:15:07
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	10 JAN 2021 12:36:19
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 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 JAN 2021 12:02:18
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 JAN 2021 15:19:03
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

03 FEB 2021 18:01:06

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

07 FEB 2021 00:07:32

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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	14 FEB 2021 11:19:28
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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	21 FEB 2021 08:58:25
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

28 FEB 2021 14:16:26

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 08:05:29

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

14 MAR 2021 08:46:23

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

21 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 MAR 2021 00:27:03
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2021 00:01
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Patient Cloud Close Date & Time	29 APR 2021 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 285

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

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

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

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

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 <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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 <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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 607

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

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

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

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

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

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

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 <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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 712

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Patient Cloud Open Date & Time	21 AUG 2022 00:01
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Patient Cloud Open Date & Time	25 SEP 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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"/>

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3202185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:40:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 14:16:45

US3202185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:44:37

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:44:37

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A VOICE MESSAGE

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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) _____

US3202185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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.

US3202185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

14:23 (24 HR)

Collection date and time (derived)

29 MAR 2021 14:23

US3202185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:19:58

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:19:58

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202185

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:40:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202185

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	UNBLND_DECIDE

US3202185

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Date of updated informed consent (<i>dd MMM yyyy</i>)	1 FEB 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>)	1 FEB 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

US3202185

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Height	
Weight	
BMI (xxx.x)	

US3202185

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Height	
Weight	
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)	1 FEB 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 10:30
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)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3202185

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Height	
Weight	
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)	1 FEB 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 11:40
Temperature (xxx.x)	35.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	105 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3202185

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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.

US3202185

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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) 1 FEB 2021

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 10:58

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

US3202185

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	1 FEB 2021 10:55

US3202185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	10:51
Collection Date and Time (derived)	1 FEB 2021 10:51

US3202185

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3202185

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	OLD29

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

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)	1 MAR 2021
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 13:05
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)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

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)	1 MAR 2021
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 14:05
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3202185

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

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.

US3202185

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 13:25 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 13:25

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) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202185

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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) _____

US3202185

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

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.

US3202185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:26:35

Generated On: 09 Jun 2021 15:40:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	29 MAR 2021 14:23

US3202185

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 13:42:41

Generated On: 09 Jun 2021 15:40:23

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) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

AEID	USA-US128-2021-MRNA-1273-P30 1000019
Adverse event	WEAKNESS
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)	6 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	13 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	6 APR 2021
Hospital Discharge Date (dd MMM yyyy)	13 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

SUBJ STATED SAW
HEPATOLOGIST FOR XPLANT
W/U. SENT TO ONCOLOGY TO
R/O ANY CANCER.
ONCOLOGIST SENT SUBJ TO
HOSPITAL FOR C/O WEAKNESS
& TESTING. RECORDS FROM
HEPATOLOGIST & HOSPITAL
HAVE BEEN REQUESTED.

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

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) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL EDEMA LEGS

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 (1)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (2)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (3)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication XIFAXAN

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD AMMONIA
LEVEL/HYPERAMMONEMIA

Dose per administration 550

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:26:34

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
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) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

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 (4)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication HAIR LOSS

Dose per administration 2.5

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 (6)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	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)	17 MAR 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 (7)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication FOLIC ACID

Prophylaxis Yes ☐
No ☒

Indication FOLIC ACID DEFICIENCY

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 (7)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL EDEMA LEGS

Dose per administration 20

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

374 of 2116

EAB) (1725)

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	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 APR 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"/>

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Name of Medication POTASSIUM CL

Prophylaxis Yes ☐
No ☒

Indication POTASSIUM DEFICIENCY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

376 of 2116

EAB) (1725)

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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"/>

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:26:34

Generated On: 09 Jun 2021 15:40:23

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
4 JAN 2021	PARACENTESIS	Medical History	

US3202185

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:40:23

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

US3202185

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:23

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 ☐

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

SAEID	USA-US128-2021-MRNA-1273-P301000019
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

SAEID	USA-US128-2021-MRNA-1273-P301000019
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	14/APR/2021 10:42
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

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 17:57:12

Generated On: 09 Jun 2021 15:40:23

SAEID	USA-US128-2021-MRNA-1273-P301000019
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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 13:10
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

US3202185 (Prod: WR-ClinSearch, LLC)

US3202185

Form: Participant Creation

Generated On: 09 Jun 2021 15:40:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:41:08
User entered 'US3202185'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:54:45

US3202185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:27

US3202185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:54:46

US3202185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:27

US3202185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'SCRN'	System	14 Aug 2020 15:36:27

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:54:47

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '56'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'YEARS'	System	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '56'	System	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Male (M)'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:02:36

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Aug 2020'	System	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2020'	System	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:38

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 14:54:46

US3202185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'I'	System	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:40:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:49:44

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:34
Data point term sent to Coder	System	05 Oct 2020 16:50:37
User entered 'CHRONIC BACK PAIN'	Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 1990'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 1990'	System	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '1990'	System	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:06

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:35:36
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 22:35:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:51:33
Data point term sent to Coder	System	05 Oct 2020 16:50:38
User entered 'GOUT'	Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 1996'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 1996'	System	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '1996'	System	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:29

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
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)	05 Oct 2020 16:52:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:52:23
Data point term sent to Coder	System	05 Oct 2020 16:51:39
User entered 'SEASONAL ALLERGIES'	Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 1992'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 1992'	System	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '1992'	System	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:50:50

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema legs - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:52:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:52:22
Data point term sent to Coder	System	05 Oct 2020 16:51:39
User entered 'BILATERAL EDEMA LEGS'	Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:31:21
User entered 'UN UNK 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	20 Oct 2020 18:31:21
User entered 'Jan 2020'	System	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	20 Oct 2020 18:31:21
User entered '2020'	System	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:51:25

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
Query 'Per DM CLR: Please specify the laterality of the KIDNEY STONE (right, left or bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:57:01
User opened query 'Per DM CLR: Please specify the laterality of the KIDNEY STONE (right, left or bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 22:37:23
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:53:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:53:27
Data point term sent to Coder	System	05 Oct 2020 16:52:40
User entered 'KIDNEY STONE'	Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:52:09

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
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)	05 Oct 2020 16:54:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:54:19
Data point term sent to Coder	System	05 Oct 2020 16:53:44
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:53:37

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:55:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:55:23
Data point term sent to Coder	System	05 Oct 2020 16:54:45
User entered 'DEPRESSION'	Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:54:02

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair loss - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:57:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:57:26
Data point term sent to Coder	System	05 Oct 2020 16:55:48
User entered 'HAIR LOSS'	Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:55:37

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Per CDM RQ: Response noted 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' however CM#3, name of med is recorded as 'XIFAXAN'? Please review and update accordingly else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:45:38
Query 'Per CDM RQ: Response noted 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' however CM#3, name of med is recorded as 'XIFAXAN'? Please review and update accordingly else clarify.'	(b) (4), (b) (6)	16 Dec 2020 18:42:13
answered with 'SUBJECT NOTED XIFAXAN IN CON MED LIST. RIFAXAN IS THE GENERIC NAME.' (Site from DM).		
User opened query 'Per CDM RQ: Response noted 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' however CM#3, name of med is recorded as 'XIFAXAN'? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:06:08
Query 'Per CDM RQ: Response noted 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' however CM#3, name of med is recorded as 'XIFAN'? Please review and update accordingly else clarify.'	(b) (4), (b) (6)	14 Dec 2020 10:05:35
canceled (Site from DM).		
User opened query 'Per CDM RQ: Response noted 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' however CM#3, name of med is recorded as 'XIFAN'? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:04:19

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:59:27
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'Subject is taking Rifaxan. It is already listed in the Con Meds on line 3 with indication for the medication.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 21:31:30
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 10:24:08
User closed query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis instead of signs and symptoms as appropriate. Please review if the medical term of "Hyperammonemia" better reflects this medical condition and reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:58:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Protein and amino acid metabolism disorders NEC, HLT: Protein metabolism disorders NEC, PT: Hyperammonaemia, LLT: Hyperammonemia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 16:42:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 16:42:57
Data point term sent to Coder	System	30 Nov 2020 16:41:26

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis instead of signs and symptoms as appropriate. Please review if the medical term of "Hyperammonemia" better reflects this medical condition and reconcile with applicable eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	30 Nov 2020 16:40:41
	(b) (4), (b) (6)	30 Nov 2020 16:40:33
User entered 'Hyperammonemia' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 16:40:33
User opened query 'Per DM CLR: Please verify MH term to reflect a medical condition or diagnosis instead of signs and symptoms as appropriate. Please review if the medical term of "Hyperammonemia" better reflects this medical condition and reconcile with applicable eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 22:37:46
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Ammonia increased, LLT: Ammonia increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:37:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:37:59
Data point term sent to Coder	System	05 Oct 2020 16:57:52
User entered 'ELEVATED BLOOD AMMONIA LEVEL'	Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 16:57:04

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
Query 'Per DM CLR: Please specify the laterality of the TOENAIL FUNGUS (right, left or bilateral toes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:57:34
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please specify the laterality of the TOENAIL FUNGUS (right, left or bilateral toes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	26 Oct 2020 22:38:08
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Fungal infection of nail - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:20:25
Data point term sent to Coder	System	05 Oct 2020 17:19:37
User entered 'TOENAIL FUNGUS'	Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:09

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Potassium deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:21:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:21:28
Data point term sent to Coder	System	05 Oct 2020 17:20:38
User entered 'POTASSIUM DEFICIENCY'	Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:39

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Folate deficiency, LLT: Folic acid deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:21:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:21:28
Data point term sent to Coder	System	05 Oct 2020 17:20:37
User entered 'FOLIC ACID DEFICIENCY'	Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2019'	System	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2019'	System	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	05 Oct 2020 17:19:53

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Liver cirrhosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:00:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:00:55
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:10:33
Data point term sent to Coder	System	12 Feb 2021 14:13:32
User entered 'elevated liver tests- cirrhosis'	Teresa Deese (b) (4) (b) (4) (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'UN UNK 2020'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'Jan 2020'	System	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '2020'	System	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered empty.	System	12 Feb 2021 14:12:43

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '11:19'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '14 Aug 2020 11:19'	System	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '178.5' cm	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29
DataPoint set to visible.	(b) (4) System	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '85.6' kg	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29
DataPoint set to visible.	(b) (4) System	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered '26.86565'	System	06 Sep 2020 16:02:29
DataPoint set to visible.	System	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'kg/m2'	System	06 Sep 2020 16:02:29
DataPoint set to visible.	System	14 Aug 2020 15:36:43

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'bpm'	System	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'breaths/min'	System	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'mmHg'	System	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User entered 'mmHg'	System	06 Sep 2020 16:02:29

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49

US3202185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49

US3202185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:00:41

US3202185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:26:31
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 15:53:48
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:00:41

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

[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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'I'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '0'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:49
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:01:31

US3202185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 15:36:54

US3202185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 15:36:54

US3202185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 15:36:54

US3202185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'VISIT1'	System	14 Aug 2020 15:36:54

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:25

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:30:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:30:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 15:29:25
User entered '104079' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:29:25

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

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)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 11:26:01
Query ' PER CDM: Please complete this section of the form' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:54:40
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:54:36
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:22:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

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)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:54:36

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:54:36

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 11:54:36

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 11:54:36

US3202185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Oct 2020 17:31:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:16:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '11:19'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Aug 2020 11:19'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '36.7' C	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '82'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'bpm'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '16'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'breaths/min'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '96'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:52:12
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	zackery harmon (b) (4) (b) (4)	18 Sep 2020 13:35:16
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:57:01
User entered '58'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12:40'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Aug 2020 12:40'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '36.6' C	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '75'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'bpm'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'breaths/min'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '95'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:52:17
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	zackery harmon (b) (4) (b) (4)	18 Sep 2020 13:35:28
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:57:01
User entered '54'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	06 Sep 2020 16:04:08

US3202185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:03:09

US3202185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:03:09

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12:00'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'ONCE'	System	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:17:55

US3202185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:49

US3202185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:49
	(b) (4)	

US3202185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '11:34'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:49

US3202185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Aug 2020 11:34'	System	06 Sep 2020 16:02:49

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '11:30'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Aug 2020 11:30'	System	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered empty.	System	06 Sep 2020 16:02:59

US3202185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 18:22:13

US3202185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	21 Aug 2020 18:22:13

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:41:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9a228669-d88e-46b5-b59d-fa16be303bc0' User entered 'Yes (Y)'	System	14 Aug 2020 16:42:00
	System	14 Aug 2020 16:42:00

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:41:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9a228669-d88e-46b5-b59d-fa16be303bc0' User entered '97.9'	System	14 Aug 2020 16:42:00
	System	14 Aug 2020 16:42:00

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:41:46', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9a228669-d88e-46b5-b59d-fa16be303bc0' User entered 'No (N)'	System	14 Aug 2020 16:42:00
	System	14 Aug 2020 16:42:00

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:41:57', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9a228669-d88e-46b5-b59d-fa16be303bc0' User entered '14 Aug 2020 12:41'	System	14 Aug 2020 16:42:00
	System	14 Aug 2020 16:42:00

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 12:20'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 14:50'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f5f6de3b-faa0-4683-aca3-0fd928cd2225' User entered 'Yes (Y)'	System	14 Aug 2020 20:05:40
	System	14 Aug 2020 20:05:40

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:05:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f5f6de3b-faa0-4683-aca3-0fd928cd2225' User entered '96.7'	System	14 Aug 2020 20:05:40
	System	14 Aug 2020 20:05:40

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:05:24', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f5f6de3b-faa0-4683-aca3-0fd928cd2225'	System	14 Aug 2020 20:05:40
User entered 'No (N)'	System	14 Aug 2020 20:05:40

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:05:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f5f6de3b-faa0-4683-aca3-0fd928cd2225' User entered '14 Aug 2020 16:05'	System	14 Aug 2020 20:05:40
	System	14 Aug 2020 20:05:40

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 15:45'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 2'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:01:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2d8efa3f-7988-453b-8ff2-758688ff22dc' User entered 'Yes (Y)'	System	15 Aug 2020 16:04:54
	System	15 Aug 2020 16:04:54

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:04:33', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2d8efa3f-7988-453b-8ff2-758688ff22dc' User entered '95.8'	System	15 Aug 2020 16:04:54
	System	15 Aug 2020 16:04:54

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:04:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2d8efa3f-7988-453b-8ff2-758688ff22dc'	System	15 Aug 2020 16:04:54
User entered 'No (N)'	System	15 Aug 2020 16:04:54

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:04:51', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2d8efa3f-7988-453b-8ff2-758688ff22dc' User entered '15 Aug 2020 12:04'	System	15 Aug 2020 16:04:54
	System	15 Aug 2020 16:04:54

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 3'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:55', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '721d8170-370c-425e-b7ff-7c602af909f8'	System	16 Aug 2020 16:07:29
User entered 'Yes (Y)'	System	16 Aug 2020 16:07:29

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:07:11', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '721d8170-370c-425e-b7ff-7c602af909f8' User entered '96.5'	System	16 Aug 2020 16:07:29
	System	16 Aug 2020 16:07:29

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:07:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '721d8170-370c-425e-b7ff-7c602af909f8'	System	16 Aug 2020 16:07:29
User entered 'No (N)'	System	16 Aug 2020 16:07:29

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:07:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '721d8170-370c-425e-b7ff-7c602af909f8'	System	16 Aug 2020 16:07:29
User entered '16 Aug 2020 12:07'	System	16 Aug 2020 16:07:29

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 4'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:28:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8e136e69-b1e7-4d2c-9c65-6205332cc9f3'	System	17 Aug 2020 19:29:16
User entered 'Yes (Y)'	System	17 Aug 2020 19:29:16

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:28:50', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8e136e69-b1e7-4d2c-9c65-6205332cc9f3' User entered '97.3'	System	17 Aug 2020 19:29:16
	System	17 Aug 2020 19:29:16

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8e136e69-b1e7-4d2c-9c65-6205332cc9f3'	System	17 Aug 2020 19:29:16
User entered 'No (N)'	System	17 Aug 2020 19:29:16

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8e136e69-b1e7-4d2c-9c65-6205332cc9f3'	System	17 Aug 2020 19:29:16
User entered '17 Aug 2020 15:29'	System	17 Aug 2020 19:29:16

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

(b)

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 5'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b1d6a506-6322-442f-b3f3-cbb3e0fb6942'	System	18 Aug 2020 17:20:42
User entered 'Yes (Y)'	System	18 Aug 2020 17:20:42

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:26', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b1d6a506-6322-442f-b3f3-cbb3e0fb6942'	System	18 Aug 2020 17:20:42
User entered '97.9'	System	18 Aug 2020 17:20:42

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b1d6a506-6322-442f-b3f3-cbb3e0fb6942'	System	18 Aug 2020 17:20:42
User entered 'No (N)'	System	18 Aug 2020 17:20:42

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b1d6a506-6322-442f-b3f3-cbb3e0fb6942'	System	18 Aug 2020 17:20:42
User entered '18 Aug 2020 13:20'	System	18 Aug 2020 17:20:42

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 6'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6e058538-18bf-401e-94cc-859578c59526' User entered 'Yes (Y)'	System	19 Aug 2020 19:05:33
	System	19 Aug 2020 19:05:33

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:04:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6e058538-18bf-401e-94cc-859578c59526' User entered '98.3'	System	19 Aug 2020 19:05:33
	System	19 Aug 2020 19:05:33

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:07', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6e058538-18bf-401e-94cc-859578c59526'	System	19 Aug 2020 19:05:33
User entered 'No (N)'	System	19 Aug 2020 19:05:33

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:29', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6e058538-18bf-401e-94cc-859578c59526' User entered '19 Aug 2020 15:05'	System	19 Aug 2020 19:05:33
	System	19 Aug 2020 19:05:33

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 7'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:43:51', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '997a987e-a3de-4968-9097-977c7a87dca2'	System	20 Aug 2020 21:44:39
User entered 'Yes (Y)'	System	20 Aug 2020 21:44:39

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:43:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '997a987e-a3de-4968-9097-977c7a87dca2'	System	20 Aug 2020 21:44:39
User entered '95.6'	System	20 Aug 2020 21:44:39

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:44:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '997a987e-a3de-4968-9097-977c7a87dca2'	System	20 Aug 2020 21:44:39
User entered 'No (N)'	System	20 Aug 2020 21:44:39

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:44:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '997a987e-a3de-4968-9097-977c7a87dca2' User entered '20 Aug 2020 17:44'	System	20 Aug 2020 21:44:39
	System	20 Aug 2020 21:44:39

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:13', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e1c550db-21c5-47f1-b241-ac9c5e1a1551'	System	14 Aug 2020 16:42:52
User entered 'None (1)'	System	14 Aug 2020 16:42:52

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e1c550db-21c5-47f1-b241-ac9c5e1a1551'	System	14 Aug 2020 16:42:52
User entered 'No (N)'	System	14 Aug 2020 16:42:52

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e1c550db-21c5-47f1-b241-ac9c5e1a1551'	System	14 Aug 2020 16:42:52
User entered 'No (N)'	System	14 Aug 2020 16:42:52

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:33', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e1c550db-21c5-47f1-b241-ac9c5e1a1551'	System	14 Aug 2020 16:42:52
User entered 'None (1)'	System	14 Aug 2020 16:42:52

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:50', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e1c550db-21c5-47f1-b241-ac9c5e1a1551' User entered '14 Aug 2020 12:42'	System	14 Aug 2020 16:42:52
	System	14 Aug 2020 16:42:52

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 12:20'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 14:50'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:08:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fb188db0-50c6-4b66-9d99-0dc734553ef1' User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 20:09:05
	System	14 Aug 2020 20:09:05

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:08:36', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fb188db0-50c6-4b66-9d99-0dc734553ef1' User entered 'No (N)'	System	14 Aug 2020 20:09:05
	System	14 Aug 2020 20:09:05

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:05:59', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fb188db0-50c6-4b66-9d99-0dc734553ef1' User entered 'No (N)'	System	14 Aug 2020 20:09:05
	System	14 Aug 2020 20:09:05

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:08:56', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fb188db0-50c6-4b66-9d99-0dc734553ef1' User entered 'None (1)'	System	14 Aug 2020 20:09:05
	System	14 Aug 2020 20:09:05

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fb188db0-50c6-4b66-9d99-0dc734553ef1' User entered '14 Aug 2020 16:09'	System	14 Aug 2020 20:09:05
	System	14 Aug 2020 20:09:05

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 15:45'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 2'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:03', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2dceeb8c-acac-4f90-bbab-bfc5baeac192'	System	15 Aug 2020 16:05:31
User entered 'None (1)'	System	15 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2dceeb8c-acac-4f90-bbab-bfc5baeac192'	System	15 Aug 2020 16:05:31
User entered 'No (N)'	System	15 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:13', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2dceeb8c-acac-4f90-bbab-bfc5baeac192'	System	15 Aug 2020 16:05:31
User entered 'No (N)'	System	15 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2dceeb8c-acac-4f90-bbab-bfc5baeac192'	System	15 Aug 2020 16:05:31
User entered 'None (1)'	System	15 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:26', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2dceeb8c-acac-4f90-bbab-bfc5baeac192'	System	15 Aug 2020 16:05:31
User entered '15 Aug 2020 12:05'	System	15 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 3'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1efb54af-1d7f-4c20-b52b-a127adbdec8a'	System	16 Aug 2020 16:05:31
User entered 'None (1)'	System	16 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:05:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1efb54af-1d7f-4c20-b52b-a127adbdec8a'	System	16 Aug 2020 16:05:31
User entered 'No (N)'	System	16 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:05:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1efb54af-1d7f-4c20-b52b-a127adbdec8a'	System	16 Aug 2020 16:05:31
User entered 'No (N)'	System	16 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:05:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1efb54af-1d7f-4c20-b52b-a127adbdec8a'	System	16 Aug 2020 16:05:31
User entered 'None (1)'	System	16 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:05:30', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1efb54af-1d7f-4c20-b52b-a127adbdec8a' User entered '16 Aug 2020 12:05'	System	16 Aug 2020 16:05:31
	System	16 Aug 2020 16:05:31

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 4'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:22', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'bbdff0f-85ea-47b0-94dc-9378c02b2156'	System	17 Aug 2020 19:29:48
User entered 'None (1)'	System	17 Aug 2020 19:29:48

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'bbdff0f-85ea-47b0-94dc-9378c02b2156'	System	17 Aug 2020 19:29:48
User entered 'No (N)'	System	17 Aug 2020 19:29:48

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:33', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'bbdff0f-85ea-47b0-94dc-9378c02b2156'	System	17 Aug 2020 19:29:48
User entered 'No (N)'	System	17 Aug 2020 19:29:48

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'bbdff0f-85ea-47b0-94dc-9378c02b2156'	System	17 Aug 2020 19:29:48
User entered 'None (1)'	System	17 Aug 2020 19:29:48

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'bbdffc0f-85ea-47b0-94dc-9378c02b2156'	System	17 Aug 2020 19:29:48
User entered '17 Aug 2020 15:29'	System	17 Aug 2020 19:29:48

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 5'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:21:54', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'dd6adcf8-5853-4109-8643-69fd330d4ffc'	System	18 Aug 2020 17:22:06
User entered 'None (1)'	System	18 Aug 2020 17:22:06

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:52', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'dd6adcf8-5853-4109-8643-69fd330d4ffc'	System	18 Aug 2020 17:22:06
User entered 'No (N)'	System	18 Aug 2020 17:22:06

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:20:57', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'dd6adcf8-5853-4109-8643-69fd330d4ffc'	System	18 Aug 2020 17:22:06
User entered 'No (N)'	System	18 Aug 2020 17:22:06

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:21:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'dd6adcf8-5853-4109-8643-69fd330d4ffc'	System	18 Aug 2020 17:22:06
User entered 'None (1)'	System	18 Aug 2020 17:22:06

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:03', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'dd6adcf8-5853-4109-8643-69fd330d4ffc' User entered '18 Aug 2020 13:22'	System	18 Aug 2020 17:22:06
	System	18 Aug 2020 17:22:06

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 6'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:43', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e5ec98ae-f543-4a80-b31f-80cd50ca7c87'	System	19 Aug 2020 19:06:24
User entered 'None (1)'	System	19 Aug 2020 19:06:24

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:49', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e5ec98ae-f543-4a80-b31f-80cd50ca7c87'	System	19 Aug 2020 19:06:24
User entered 'No (N)'	System	19 Aug 2020 19:06:24

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:05:56', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e5ec98ae-f543-4a80-b31f-80cd50ca7c87'	System	19 Aug 2020 19:06:24
User entered 'No (N)'	System	19 Aug 2020 19:06:24

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:02', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e5ec98ae-f543-4a80-b31f-80cd50ca7c87'	System	19 Aug 2020 19:06:24
User entered 'None (1)'	System	19 Aug 2020 19:06:24

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e5ec98ae-f543-4a80-b31f-80cd50ca7c87'	System	19 Aug 2020 19:06:24
User entered '19 Aug 2020 15:06'	System	19 Aug 2020 19:06:24

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 7'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:44:50', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1d21b745-3ce0-4224-b869-b586e21b306d'	System	20 Aug 2020 21:45:34
User entered 'None (1)'	System	20 Aug 2020 21:45:34

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:44:56', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1d21b745-3ce0-4224-b869-b586e21b306d' User entered 'No (N)'	System	20 Aug 2020 21:45:34
	System	20 Aug 2020 21:45:34

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1d21b745-3ce0-4224-b869-b586e21b306d' User entered 'No (N)'	System	20 Aug 2020 21:45:34
	System	20 Aug 2020 21:45:34

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1d21b745-3ce0-4224-b869-b586e21b306d' User entered 'None (1)'	System	20 Aug 2020 21:45:34
	System	20 Aug 2020 21:45:34

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:30', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '1d21b745-3ce0-4224-b869-b586e21b306d' User entered '20 Aug 2020 17:45'	System	20 Aug 2020 21:45:34
	System	20 Aug 2020 21:45:34

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:42:57', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered 'None (0)'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6'	System	14 Aug 2020 16:43:49
User entered 'None (0)'	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered 'None (0)'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered 'None (0)'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:17', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered 'None (0)'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:21', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered 'None (0)'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6'	System	14 Aug 2020 16:43:49
User entered 'No (N)'	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T12:43:47', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd4ce09b1-213d-42dc-83a1-7fd97e99d5e6' User entered '14 Aug 2020 12:43'	System	14 Aug 2020 16:43:49
	System	14 Aug 2020 16:43:49

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 12:20'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 14:50'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:17', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:23', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:43', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900' User entered 'None (0)'	System	14 Aug 2020 20:10:04
	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:09:55', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900'	System	14 Aug 2020 20:10:04
User entered 'No (N)'	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-14T16:10:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '66c9a225-a673-499a-ad6c-1f5bcd654900'	System	14 Aug 2020 20:10:04
User entered '14 Aug 2020 16:10'	System	14 Aug 2020 20:10:04

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Aug 2020 15:45'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 2'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:36', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2'	System	15 Aug 2020 16:06:07
User entered 'None (0)'	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2' User entered 'None (0)'	System	15 Aug 2020 16:06:07
	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:44', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2'	System	15 Aug 2020 16:06:07
User entered 'None (0)'	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:48', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2' User entered 'None (0)'	System	15 Aug 2020 16:06:07
	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:51', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2' User entered 'None (0)'	System	15 Aug 2020 16:06:07
	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:05:55', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2'	System	15 Aug 2020 16:06:07
User entered 'None (0)'	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:06:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2'	System	15 Aug 2020 16:06:07
User entered 'No (N)'	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-15T12:06:05', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba3cfa03-421a-40dc-9450-787de3a5aaa2'	System	15 Aug 2020 16:06:07
User entered '15 Aug 2020 12:06'	System	15 Aug 2020 16:06:07

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 3'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:07', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:11', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:17', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120' User entered 'None (0)'	System	16 Aug 2020 16:06:40
	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:21', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120'	System	16 Aug 2020 16:06:40
User entered 'No (N)'	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-16T12:06:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c0f4d28a-43b1-4a24-901f-6f2db3ed4120'	System	16 Aug 2020 16:06:40
User entered '16 Aug 2020 12:06'	System	16 Aug 2020 16:06:40

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 4'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:29:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:02', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:09', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:23', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'None (0)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered 'No (N)'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-17T15:30:36', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '87801785-3c02-408d-b565-6cb202ec83fa' User entered '17 Aug 2020 15:30'	System	17 Aug 2020 19:30:38
	System	17 Aug 2020 19:30:38

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 5'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:10', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8'	System	18 Aug 2020 17:23:01
User entered 'None (0)'	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8'	System	18 Aug 2020 17:23:01
User entered 'None (0)'	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8' User entered 'None (0)'	System	18 Aug 2020 17:23:01
	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:33', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8' User entered 'None (0)'	System	18 Aug 2020 17:23:01
	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8' User entered 'None (0)'	System	18 Aug 2020 17:23:01
	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8' User entered 'None (0)'	System	18 Aug 2020 17:23:01
	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:48', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8' User entered 'No (N)'	System	18 Aug 2020 17:23:01
	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-18T13:22:57', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e6f1b68e-bf78-4aa7-94ab-ba3266ffdee8'	System	18 Aug 2020 17:23:01
User entered '18 Aug 2020 13:22'	System	18 Aug 2020 17:23:01

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 6'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:29', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:47', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:54', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:06:59', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered 'None (0)'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:07:05', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69'	System	19 Aug 2020 19:07:16
User entered 'No (N)'	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-19T15:07:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '166f1129-0d26-47c7-8560-001a1ff8fa69' User entered '19 Aug 2020 15:07'	System	19 Aug 2020 19:07:16
	System	19 Aug 2020 19:07:16

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 7'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:48', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:45:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:46:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:46:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:46:17', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'None (0)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:46:24', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered 'No (N)'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-08-20T17:46:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e282d368-fd0e-4eac-84cf-cc4416dc8d4c' User entered '20 Aug 2020 17:46'	System	20 Aug 2020 21:46:43
	System	20 Aug 2020 21:46:43

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:17:55

US3202185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 18:22:27

US3202185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '21 Aug 2020'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	21 Aug 2020 18:22:27

US3202185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 18:22:27

US3202185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 18:22:27

US3202185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 18:22:34

US3202185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	21 Aug 2020 18:22:34

US3202185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:22

US3202185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '28 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:22

US3202185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:22

US3202185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:22

US3202185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:10

US3202185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	14 Sep 2020 15:53:10

US3202185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:45

US3202185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '4 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:45

US3202185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:45

US3202185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:33:45

US3202185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:36

US3202185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	14 Sep 2020 15:53:36

US3202185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:48

US3202185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:48

US3202185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:48

US3202185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'VISIT2'	System	14 Sep 2020 15:53:48

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '14 Sep 2020'	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '10:34'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Sep 2020 10:34'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '36.8' C	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '72'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'bpm'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'breaths/min'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '116'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '73'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '14 Sep 2020'	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '11:58'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Sep 2020 11:58'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '37.1' C	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered empty.	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '82'	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'bpm'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'breaths/min'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '115'	(b) (4) zackery harmon (b) (4)	13 Mar 2021 16:12:12
	(b) (4)	

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '72'	(b) (4) zackery harmon (b) (4) (b) (4)	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	13 Mar 2021 16:12:12

US3202185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:56

US3202185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:53:56

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '11:17'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Sep 2020 11:17'	System	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	28 Sep 2020 04:15:44
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	28 Sep 2020 04:15:44
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 04:15:44
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Sep 2020 15:55:24
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 15:55:24
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	14 Sep 2020 15:54:58
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	14 Sep 2020 15:54:58
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	14 Sep 2020 15:54:58
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	14 Sep 2020 15:54:28
User entered 'Right Arm (RIGHT ARM)'	Tiffany Jewell (b) (4)	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'ONCE'	System	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 15:54:28

US3202185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:06

US3202185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:20:54
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'all 24 aliquots shipped to central lab and they report that 23 of 24 were received for this accession number 1F67955' (Site from DM).	Erica Osmundsen (b) (4)	07 Oct 2020 14:25:17
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:27:24
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 15:59:06

US3202185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '10:46'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:06

US3202185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Sep 2020 10:46'	System	14 Sep 2020 15:59:06

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '10:43'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '14 Sep 2020 10:43'	System	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered empty.	System	14 Sep 2020 15:59:18

US3202185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 15:59:41

US3202185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	14 Sep 2020 15:59:41

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:03:36', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9754b44d-b076-4d76-8bb0-2b632a4887aa'	System	14 Sep 2020 16:08:27
User entered 'Yes (Y)'	System	14 Sep 2020 16:08:27

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:03:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9754b44d-b076-4d76-8bb0-2b632a4887aa' User entered '98.8'	System	14 Sep 2020 16:08:27
	System	14 Sep 2020 16:08:27

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:03:59', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9754b44d-b076-4d76-8bb0-2b632a4887aa'	System	14 Sep 2020 16:08:27
User entered 'No (N)'	System	14 Sep 2020 16:08:27

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:10', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9754b44d-b076-4d76-8bb0-2b632a4887aa'	System	14 Sep 2020 16:08:27
User entered '14 Sep 2020 12:04'	System	14 Sep 2020 16:08:27

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 14:07'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:18:49', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5e85043c-7f1b-4e6e-87b2-a4d7e919a2c1' User entered 'Yes (Y)'	System	15 Sep 2020 01:19:14
	System	15 Sep 2020 01:19:14

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:18:56', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5e85043c-7f1b-4e6e-87b2-a4d7e919a2c1' User entered '98.2'	System	15 Sep 2020 01:19:14
	System	15 Sep 2020 01:19:14

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:02', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5e85043c-7f1b-4e6e-87b2-a4d7e919a2c1' User entered 'No (N)'	System	15 Sep 2020 01:19:14
	System	15 Sep 2020 01:19:14

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:10', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5e85043c-7f1b-4e6e-87b2-a4d7e919a2c1' User entered '14 Sep 2020 21:19'	System	15 Sep 2020 01:19:14
	System	15 Sep 2020 01:19:14

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 2'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:23:54', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '758ed3b0-1b50-42b6-85dc-16a8bf45a6cc' User entered 'Yes (Y)'	System	15 Sep 2020 16:25:28
	System	15 Sep 2020 16:25:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:16', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '758ed3b0-1b50-42b6-85dc-16a8bf45a6cc' User entered '98.2'	System	15 Sep 2020 16:25:28
	System	15 Sep 2020 16:25:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '758ed3b0-1b50-42b6-85dc-16a8bf45a6cc'	System	15 Sep 2020 16:25:28
User entered 'No (N)'	System	15 Sep 2020 16:25:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '758ed3b0-1b50-42b6-85dc-16a8bf45a6cc'	System	15 Sep 2020 16:25:28
User entered '15 Sep 2020 12:25'	System	15 Sep 2020 16:25:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 3'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:02:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '18c58fc0-ab51-4abf-a4bd-1749e4431180' User entered 'Yes (Y)'	System	16 Sep 2020 16:05:31
	System	16 Sep 2020 16:05:31

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:03:15', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '18c58fc0-ab51-4abf-a4bd-1749e4431180' User entered '97.4'	System	16 Sep 2020 16:05:31
	System	16 Sep 2020 16:05:31

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:03:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '18c58fc0-ab51-4abf-a4bd-1749e4431180' User entered 'No (N)'	System	16 Sep 2020 16:05:31
	System	16 Sep 2020 16:05:31

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:03:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '18c58fc0-ab51-4abf-a4bd-1749e4431180' User entered '16 Sep 2020 12:03'	System	16 Sep 2020 16:05:31
	System	16 Sep 2020 16:05:31

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 4'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:02:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3af707a3-0d75-4c6f-852f-1c3287942a7e' User entered 'Yes (Y)'	System	17 Sep 2020 16:04:12
	System	17 Sep 2020 16:04:12

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:02:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3af707a3-0d75-4c6f-852f-1c3287942a7e' User entered '97.6'	System	17 Sep 2020 16:04:12
	System	17 Sep 2020 16:04:12

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:02:43', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3af707a3-0d75-4c6f-852f-1c3287942a7e'	System	17 Sep 2020 16:04:12
User entered 'No (N)'	System	17 Sep 2020 16:04:12

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:02:49', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3af707a3-0d75-4c6f-852f-1c3287942a7e' User entered '17 Sep 2020 12:02'	System	17 Sep 2020 16:04:12
	System	17 Sep 2020 16:04:12

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 5'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:39:41', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fc1e81fb-1433-422d-92b8-c7907af5bbab' User entered 'Yes (Y)'	System	19 Sep 2020 08:40:07
	System	19 Sep 2020 08:40:07

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:39:49', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fc1e81fb-1433-422d-92b8-c7907af5bbab' User entered '97.6'	System	19 Sep 2020 08:40:07
	System	19 Sep 2020 08:40:07

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:39:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fc1e81fb-1433-422d-92b8-c7907af5bbab'	System	19 Sep 2020 08:40:07
User entered 'No (N)'	System	19 Sep 2020 08:40:07

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'fc1e81fb-1433-422d-92b8-c7907af5bbab' User entered '19 Sep 2020 04:40'	System	19 Sep 2020 08:40:07
	System	19 Sep 2020 08:40:07

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 6'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:03:11', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '74f53d6f-4fc0-4357-9e82-cdf5d5e7d58a' User entered 'Yes (Y)'	System	19 Sep 2020 16:04:15
	System	19 Sep 2020 16:04:15

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:04:05', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '74f53d6f-4fc0-4357-9e82-cdf5d5e7d58a' User entered '98.0'	System	19 Sep 2020 16:04:15
	System	19 Sep 2020 16:04:15

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:04:09', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '74f53d6f-4fc0-4357-9e82-cdf5d5e7d58a'	System	19 Sep 2020 16:04:15
User entered 'No (N)'	System	19 Sep 2020 16:04:15

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:04:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '74f53d6f-4fc0-4357-9e82-cdf5d5e7d58a' User entered '19 Sep 2020 12:04'	System	19 Sep 2020 16:04:15
	System	19 Sep 2020 16:04:15

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 7'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:24', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2568c847-16d9-4696-9ec9-35d301f86159' User entered 'None (1)'	System	14 Sep 2020 16:09:03
	System	14 Sep 2020 16:09:03

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2568c847-16d9-4696-9ec9-35d301f86159' User entered 'No (N)'	System	14 Sep 2020 16:09:03
	System	14 Sep 2020 16:09:03

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:43', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2568c847-16d9-4696-9ec9-35d301f86159' User entered 'No (N)'	System	14 Sep 2020 16:09:03
	System	14 Sep 2020 16:09:03

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:49', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2568c847-16d9-4696-9ec9-35d301f86159'	System	14 Sep 2020 16:09:03
User entered 'None (1)'	System	14 Sep 2020 16:09:03

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:04:58', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '2568c847-16d9-4696-9ec9-35d301f86159' User entered '14 Sep 2020 12:04'	System	14 Sep 2020 16:09:03
	System	14 Sep 2020 16:09:03

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 14:07'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:26', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '465b92ac-6a2c-4ec1-96d3-9a13029dfeca' User entered 'None (1)'	System	15 Sep 2020 01:19:55
	System	15 Sep 2020 01:19:55

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '465b92ac-6a2c-4ec1-96d3-9a13029dfeca' User entered 'No (N)'	System	15 Sep 2020 01:19:55
	System	15 Sep 2020 01:19:55

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '465b92ac-6a2c-4ec1-96d3-9a13029dfeca' User entered 'No (N)'	System	15 Sep 2020 01:19:55
	System	15 Sep 2020 01:19:55

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '465b92ac-6a2c-4ec1-96d3-9a13029dfeca' User entered 'None (1)'	System	15 Sep 2020 01:19:55
	System	15 Sep 2020 01:19:55

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:19:51', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '465b92ac-6a2c-4ec1-96d3-9a13029dfeca'	System	15 Sep 2020 01:19:55
User entered '14 Sep 2020 21:19'	System	15 Sep 2020 01:19:55

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 2'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3f28ef03-2691-4b53-82cb-c980e373b9a3'	System	15 Sep 2020 16:26:05
User entered 'None (1)'	System	15 Sep 2020 16:26:05

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3f28ef03-2691-4b53-82cb-c980e373b9a3' User entered 'No (N)'	System	15 Sep 2020 16:26:05
	System	15 Sep 2020 16:26:05

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:44', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3f28ef03-2691-4b53-82cb-c980e373b9a3' User entered 'No (N)'	System	15 Sep 2020 16:26:05
	System	15 Sep 2020 16:26:05

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3f28ef03-2691-4b53-82cb-c980e373b9a3'	System	15 Sep 2020 16:26:05
User entered 'None (1)'	System	15 Sep 2020 16:26:05

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:25:59', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3f28ef03-2691-4b53-82cb-c980e373b9a3'	System	15 Sep 2020 16:26:05
User entered '15 Sep 2020 12:25'	System	15 Sep 2020 16:26:05

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 3'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:03:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c4cd7857-33f4-4a5f-8c75-4d8413ac6371' User entered 'None (1)'	System	16 Sep 2020 16:06:01
	System	16 Sep 2020 16:06:01

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:03:50', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c4cd7857-33f4-4a5f-8c75-4d8413ac6371' User entered 'No (N)'	System	16 Sep 2020 16:06:01
	System	16 Sep 2020 16:06:01

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:13', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c4cd7857-33f4-4a5f-8c75-4d8413ac6371' User entered 'No (N)'	System	16 Sep 2020 16:06:01
	System	16 Sep 2020 16:06:01

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:21', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c4cd7857-33f4-4a5f-8c75-4d8413ac6371' User entered 'None (1)'	System	16 Sep 2020 16:06:01
	System	16 Sep 2020 16:06:01

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c4cd7857-33f4-4a5f-8c75-4d8413ac6371' User entered '16 Sep 2020 12:04'	System	16 Sep 2020 16:06:01
	System	16 Sep 2020 16:06:01

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 4'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:02:55', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a4f71f37-3801-4b95-ba4f-5d623467689e' User entered 'None (1)'	System	17 Sep 2020 16:04:44
	System	17 Sep 2020 16:04:44

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a4f71f37-3801-4b95-ba4f-5d623467689e' User entered 'No (N)'	System	17 Sep 2020 16:04:44
	System	17 Sep 2020 16:04:44

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a4f71f37-3801-4b95-ba4f-5d623467689e' User entered 'No (N)'	System	17 Sep 2020 16:04:44
	System	17 Sep 2020 16:04:44

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:09', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a4f71f37-3801-4b95-ba4f-5d623467689e' User entered 'None (1)'	System	17 Sep 2020 16:04:44
	System	17 Sep 2020 16:04:44

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:13', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a4f71f37-3801-4b95-ba4f-5d623467689e' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:44
	System	17 Sep 2020 16:04:44

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 5'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:36:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '7cea99e6-0289-4cbe-8ff4-01585bcf1b28'	System	19 Sep 2020 08:37:04
User entered 'None (1)'	System	19 Sep 2020 08:37:04

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:36:36', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '7cea99e6-0289-4cbe-8ff4-01585bcf1b28'	System	19 Sep 2020 08:37:04
User entered 'No (N)'	System	19 Sep 2020 08:37:04

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:36:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '7cea99e6-0289-4cbe-8ff4-01585bcf1b28'	System	19 Sep 2020 08:37:04
User entered 'No (N)'	System	19 Sep 2020 08:37:04

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:36:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '7cea99e6-0289-4cbe-8ff4-01585bcf1b28'	System	19 Sep 2020 08:37:04
User entered 'None (1)'	System	19 Sep 2020 08:37:04

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:37:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '7cea99e6-0289-4cbe-8ff4-01585bcf1b28'	System	19 Sep 2020 08:37:04
User entered '19 Sep 2020 04:37'	System	19 Sep 2020 08:37:04

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 6'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a7b22bc2-4dd3-4930-8821-52234df88edd' User entered 'None (1)'	System	19 Sep 2020 16:02:58
	System	19 Sep 2020 16:02:58

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a7b22bc2-4dd3-4930-8821-52234df88edd' User entered 'No (N)'	System	19 Sep 2020 16:02:58
	System	19 Sep 2020 16:02:58

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:22', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a7b22bc2-4dd3-4930-8821-52234df88edd' User entered 'No (N)'	System	19 Sep 2020 16:02:58
	System	19 Sep 2020 16:02:58

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a7b22bc2-4dd3-4930-8821-52234df88edd' User entered 'None (1)'	System	19 Sep 2020 16:02:58
	System	19 Sep 2020 16:02:58

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:29', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'a7b22bc2-4dd3-4930-8821-52234df88edd' User entered '19 Sep 2020 12:02'	System	19 Sep 2020 16:02:58
	System	19 Sep 2020 16:02:58

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 7'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:09', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:13', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:21', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:28', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2' User entered 'None (0)'	System	14 Sep 2020 16:09:37
	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2'	System	14 Sep 2020 16:09:37
User entered 'No (N)'	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T12:05:44', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c17fb47e-59d2-4e2c-8873-0a1b6b4b0cf2'	System	14 Sep 2020 16:09:37
User entered '14 Sep 2020 12:05'	System	14 Sep 2020 16:09:37

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 11:37'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 14:07'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:16', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'None (0)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered 'No (N)'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-14T21:20:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '46885a66-ecfe-4ab8-a578-ed3e2ca55d1b' User entered '14 Sep 2020 21:20'	System	15 Sep 2020 01:20:39
	System	15 Sep 2020 01:20:39

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '14 Sep 2020 15:02'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 2'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:07', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06'	System	15 Sep 2020 16:26:47
User entered 'None (0)'	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06' User entered 'None (0)'	System	15 Sep 2020 16:26:47
	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:16', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06' User entered 'None (0)'	System	15 Sep 2020 16:26:47
	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06'	System	15 Sep 2020 16:26:47
User entered 'None (0)'	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:24', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06' User entered 'None (0)'	System	15 Sep 2020 16:26:47
	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:28', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06'	System	15 Sep 2020 16:26:47
User entered 'None (0)'	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:37', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06'	System	15 Sep 2020 16:26:47
User entered 'No (N)'	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-15T12:26:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'b39cd42f-dcf7-45c3-bd33-e846e1b17a06'	System	15 Sep 2020 16:26:47
User entered '15 Sep 2020 12:26'	System	15 Sep 2020 16:26:47

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 3'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:41', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:04:46', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:05:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:05:09', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:05:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'None (0)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:05:22', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered 'No (N)'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-16T12:05:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f30b0301-dd55-40e5-b578-3f865a232508' User entered '16 Sep 2020 12:05'	System	16 Sep 2020 16:06:40
	System	16 Sep 2020 16:06:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 4'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:23', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:30', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:33', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:43', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered 'No (N)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-17T12:03:50', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '5c5cf139-b7c8-4b47-a0f6-418ad66f3a8c' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 5'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:16', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:24', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:28', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'None (0)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered 'No (N)'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T04:40:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '3b0eda6c-4da6-4436-ac2f-3c0117bd21ab' User entered '19 Sep 2020 04:40'	System	19 Sep 2020 08:40:40
	System	19 Sep 2020 08:40:40

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 6'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:38', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:48', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:54', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered 'None (0)'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:02:58', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91'	System	19 Sep 2020 16:03:27
User entered 'No (N)'	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-09-19T12:03:03', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '6bf06e18-8d33-4279-bc4b-fec5fb9add91' User entered '19 Sep 2020 12:03'	System	19 Sep 2020 16:03:27
	System	19 Sep 2020 16:03:27

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Sep 2020 15:54:28
User entered 'Day 7'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 15:54:28

US3202185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 15:54:28

US3202185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 16:22:57

US3202185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '21 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 16:22:57
	(b) (4)	

US3202185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 16:22:57

US3202185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 16:22:57

US3202185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 16:23:02

US3202185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	21 Sep 2020 16:23:02

US3202185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 19:37:56

US3202185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '28 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 19:37:56
	(b) (4)	

US3202185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 19:37:56

US3202185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	Lilian Nukuna (b) (4)	28 Sep 2020 19:37:56

US3202185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 19:38:02
	(b) (4)	

US3202185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	28 Sep 2020 19:38:02

US3202185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit 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)	27 Oct 2020 05:55:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit 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 'ENTERING DAY 57 NOW' (Site from DM).	Erica Osmundsen (b) (4)	20 Oct 2020 18:34:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit 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)	20 Oct 2020 11:25:41
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	05 Oct 2020 18:25:58

US3202185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '5 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	05 Oct 2020 18:25:58

US3202185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	05 Oct 2020 18:25:58

US3202185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	Lilian Nukuna (b) (4)	05 Oct 2020 18:25:58

US3202185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	05 Oct 2020 18:26:04

US3202185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	05 Oct 2020 18:26:04

US3202185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:34:45

US3202185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:34:45

US3202185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:34:45

US3202185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'VISIT3'	System	20 Oct 2020 18:34:45

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '10:34'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '12 Oct 2020 10:34'	System	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '36.8' C	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Oral (Oral)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '102'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'bpm'	System	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '18'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'breaths/min'	System	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '139'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '77'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'mmHg'	System	20 Oct 2020 18:35:15

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08

US3202185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08

US3202185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:25

US3202185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:25

US3202185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:35

US3202185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '12 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:35

US3202185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered '10:40'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:35

US3202185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered '12 Oct 2020 10:40'	System	20 Oct 2020 18:35:35

US3202185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:33
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 18:35:39

US3202185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	20 Oct 2020 18:35:39

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 64'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-15T14:18:59', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '930d5a92-5540-4265-9df9-5ea9f18eedab' User entered 'No (N)'	System	15 Oct 2020 18:19:23
	System	15 Oct 2020 18:19:23

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-15T14:19:04', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '930d5a92-5540-4265-9df9-5ea9f18eedab'	System	15 Oct 2020 18:19:23
User entered 'No (N)'	System	15 Oct 2020 18:19:23

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-15T14:19:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '930d5a92-5540-4265-9df9-5ea9f18eedab' User entered '15 Oct 2020 14:19:19'	System	15 Oct 2020 18:19:23
	System	15 Oct 2020 18:19:23

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 71'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-21T09:52:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '37ab4e3d-1204-443a-baaf-c86c29525a17'	System	21 Oct 2020 13:53:22
User entered 'No (N)'	System	21 Oct 2020 13:53:22

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-21T09:53:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '37ab4e3d-1204-443a-baaf-c86c29525a17'	System	21 Oct 2020 13:53:22
User entered 'No (N)'	System	21 Oct 2020 13:53:22

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-21T09:53:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '37ab4e3d-1204-443a-baaf-c86c29525a17' User entered '21 Oct 2020 09:53:18'	System	21 Oct 2020 13:53:22
	System	21 Oct 2020 13:53:22

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 78'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-28T16:05:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9370711f-0b7a-412a-b244-51f76eb7b6b3'	System	28 Oct 2020 20:05:28
User entered 'No (N)'	System	28 Oct 2020 20:05:28

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-28T16:05:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9370711f-0b7a-412a-b244-51f76eb7b6b3'	System	28 Oct 2020 20:05:28
User entered 'No (N)'	System	28 Oct 2020 20:05:28

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-10-28T16:05:26', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9370711f-0b7a-412a-b244-51f76eb7b6b3' User entered '28 Oct 2020 16:05:26'	System	28 Oct 2020 20:05:28
	System	28 Oct 2020 20:05:28

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 92'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-15T09:17:41', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '79629db2-57c0-4c1e-bc3e-7e9a657aa37c'	System	15 Nov 2020 14:18:43
User entered 'Yes (Y)'	System	15 Nov 2020 14:18:43

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-15T09:17:51', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '79629db2-57c0-4c1e-bc3e-7e9a657aa37c'	System	15 Nov 2020 14:18:43
User entered 'No (N)'	System	15 Nov 2020 14:18:43

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-15T09:18:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '79629db2-57c0-4c1e-bc3e-7e9a657aa37c'	System	15 Nov 2020 14:18:43
User entered 'No (N)'	System	15 Nov 2020 14:18:43

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-15T09:18:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '79629db2-57c0-4c1e-bc3e-7e9a657aa37c'	System	15 Nov 2020 14:18:43
User entered 'No (N)'	System	15 Nov 2020 14:18:43

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-15T09:18:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '79629db2-57c0-4c1e-bc3e-7e9a657aa37c' User entered '15 Nov 2020 09:18:40'	System	15 Nov 2020 14:18:43
	System	15 Nov 2020 14:18:43

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:26
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32
Data entry locked.	System	14 Aug 2020 16:17:55
User entered 'Day 99'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 16:17:55

US3202185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:16:32
Data entry locked.	System	14 Aug 2020 16:17:55
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 16:17:55

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-22T07:40:02', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9c970fc9-4535-4a64-97c5-61ed050fc42d'	System	22 Nov 2020 12:40:23
User entered 'No (N)'	System	22 Nov 2020 12:40:23

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-22T07:40:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9c970fc9-4535-4a64-97c5-61ed050fc42d' User entered 'No (N)'	System	22 Nov 2020 12:40:23

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-11-22T07:40:21', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9c970fc9-4535-4a64-97c5-61ed050fc42d' User entered '22 Nov 2020 07:40:21'	System	22 Nov 2020 12:40:23
	System	22 Nov 2020 12:40:23

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-01T15:51:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '67cdda48-54d1-45b4-b49b-4fe8234e51aa' User entered 'No (N)'	System	01 Dec 2020 20:52:11
	System	01 Dec 2020 20:52:11

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-01T15:52:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '67cdda48-54d1-45b4-b49b-4fe8234e51aa' User entered 'No (N)'	System	01 Dec 2020 20:52:11
	System	01 Dec 2020 20:52:11

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-01T15:52:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '67cdda48-54d1-45b4-b49b-4fe8234e51aa' User entered '01 Dec 2020 15:52:08'	System	01 Dec 2020 20:52:11
	System	01 Dec 2020 20:52:11

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-06T13:57:01', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f61c078-9212-4caf-96b3-a9495f0e802e' User entered 'No (N)'	System	06 Dec 2020 18:57:14
	System	06 Dec 2020 18:57:14

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-06T13:57:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f61c078-9212-4caf-96b3-a9495f0e802e' User entered 'No (N)'	System	06 Dec 2020 18:57:14
	System	06 Dec 2020 18:57:14

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-06T13:57:12', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f61c078-9212-4caf-96b3-a9495f0e802e' User entered '06 Dec 2020 13:57:12'	System	06 Dec 2020 18:57:14
	System	06 Dec 2020 18:57:14

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-14T11:49:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '973f459f-2f69-49be-986c-836cb61d0646'	System	14 Dec 2020 16:49:47
User entered 'No (N)'	System	14 Dec 2020 16:49:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-14T11:49:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '973f459f-2f69-49be-986c-836cb61d0646'	System	14 Dec 2020 16:49:47
User entered 'No (N)'	System	14 Dec 2020 16:49:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-14T11:49:45', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '973f459f-2f69-49be-986c-836cb61d0646'	System	14 Dec 2020 16:49:47
User entered '14 Dec 2020 11:49:45'	System	14 Dec 2020 16:49:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-22T11:16:28', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8fae6f83-7a0e-482e-b3ca-fcaf00c75d08'	System	22 Dec 2020 16:16:47
User entered 'No (N)'	System	22 Dec 2020 16:16:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-22T11:16:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8fae6f83-7a0e-482e-b3ca-fcaf00c75d08'	System	22 Dec 2020 16:16:47
User entered 'No (N)'	System	22 Dec 2020 16:16:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-22T11:16:42', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '8fae6f83-7a0e-482e-b3ca-fcaf00c75d08'	System	22 Dec 2020 16:16:47
User entered '22 Dec 2020 11:16:42'	System	22 Dec 2020 16:16:47

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-28T16:23:46', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ee035a7c-e1d7-4ba6-929f-f915806c515f' User entered 'No (N)'	System	28 Dec 2020 21:24:07
	System	28 Dec 2020 21:24:07

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-28T16:23:52', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ee035a7c-e1d7-4ba6-929f-f915806c515f' User entered 'No (N)'	System	28 Dec 2020 21:24:07

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2020-12-28T16:24:03', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ee035a7c-e1d7-4ba6-929f-f915806c515f' User entered '28 Dec 2020 16:24:03'	System	28 Dec 2020 21:24:07
	System	28 Dec 2020 21:24:07

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-06T18:14:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '618dff05-b46d-4ef3-9b78-20b6ad653a2b' User entered 'Yes (Y)'	System	06 Jan 2021 23:15:43
	System	06 Jan 2021 23:15:43

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-06T18:14:08', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '618dff05-b46d-4ef3-9b78-20b6ad653a2b'	System	06 Jan 2021 23:15:43
User entered 'No (N)'	System	06 Jan 2021 23:15:43

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-06T18:14:41', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '618dff05-b46d-4ef3-9b78-20b6ad653a2b' User entered 'No (N)'	System	06 Jan 2021 23:15:43

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-06T18:14:57', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '618dff05-b46d-4ef3-9b78-20b6ad653a2b' User entered 'No (N)'	System	06 Jan 2021 23:15:43

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-06T18:15:07', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '618dff05-b46d-4ef3-9b78-20b6ad653a2b' User entered '06 Jan 2021 18:15:07'	System	06 Jan 2021 23:15:43
	System	06 Jan 2021 23:15:43

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:35:31', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd' User entered 'Yes (Y)'	System	10 Jan 2021 17:36:29
	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:35:35', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd' User entered 'No (N)'	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:35:40', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd' User entered 'No (N)'	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:35:52', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd' User entered 'Yes (Y)'	System	10 Jan 2021 17:36:29
	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Please 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:36:10', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd'	System	10 Jan 2021 17:36:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-10T12:36:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '78924446-d678-483a-a62a-e3ba8278eefd' User entered '10 Jan 2021 12:36:19'	System	10 Jan 2021 17:36:29
	System	10 Jan 2021 17:36:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:01:02', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a' User entered 'Yes (Y)'	System	19 Jan 2021 17:02:56
	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:01:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a' User entered 'Yes (Y)'	System	19 Jan 2021 17:02:56
	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Please 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:01:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a'	System	19 Jan 2021 17:02:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:01:39', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a' User entered 'No (N)'	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:01:54', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a' User entered 'Yes (Y)'	System	19 Jan 2021 17:02:56
	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Please 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:02:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a'	System	19 Jan 2021 17:02:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-19T12:02:18', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'f6c5090c-6715-46d5-b1f0-14d6fd6d949a' User entered '19 Jan 2021 12:02:18'	System	19 Jan 2021 17:02:56
	System	19 Jan 2021 17:02:56

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:18:07', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d' User entered 'Yes (Y)'	System	24 Jan 2021 20:19:15
	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:18:16', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d' User entered 'Yes (Y)'	System	24 Jan 2021 20:19:15
	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Please 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:18:23', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d'	System	24 Jan 2021 20:19:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:18:34', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d' User entered 'No (N)'	System	24 Jan 2021 20:19:15
	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:18:53', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d' User entered 'No (N)'	System	24 Jan 2021 20:19:15
	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-01-24T15:19:03', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '0db1313f-d3a0-463f-b498-8d85bc0c610d' User entered '24 Jan 2021 15:19:03'	System	24 Jan 2021 20:19:15
	System	24 Jan 2021 20:19:15

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-03T18:00:44', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '44330be4-792b-49e0-8bb4-69f15f00e777' User entered 'No (N)'	System	03 Feb 2021 23:02:42
	System	03 Feb 2021 23:02:42

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-03T18:00:58', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '44330be4-792b-49e0-8bb4-69f15f00e777'	System	03 Feb 2021 23:02:42
User entered 'No (N)'	System	03 Feb 2021 23:02:42

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-03T18:01:06', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '44330be4-792b-49e0-8bb4-69f15f00e777'	System	03 Feb 2021 23:02:42
User entered '03 Feb 2021 18:01:06'	System	03 Feb 2021 23:02:42

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-07T00:07:19', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '052053a4-1285-4757-85ce-d4eaec6b12b5'	System	07 Feb 2021 05:07:36
User entered 'No (N)'	System	07 Feb 2021 05:07:36

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-07T00:07:27', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '052053a4-1285-4757-85ce-d4eaec6b12b5'	System	07 Feb 2021 05:07:36
User entered 'No (N)'	System	07 Feb 2021 05:07:36

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-07T00:07:32', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '052053a4-1285-4757-85ce-d4eaec6b12b5'	System	07 Feb 2021 05:07:36
User entered '07 Feb 2021 00:07:32'	System	07 Feb 2021 05:07:36

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-14T11:19:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '59c012bd-3a16-4dd5-ad87-ba824723ab6f' User entered 'No (N)'	System	14 Feb 2021 16:19:31
	System	14 Feb 2021 16:19:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-14T11:19:23', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '59c012bd-3a16-4dd5-ad87-ba824723ab6f' User entered 'No (N)'	System	14 Feb 2021 16:19:31
	System	14 Feb 2021 16:19:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-14T11:19:28', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '59c012bd-3a16-4dd5-ad87-ba824723ab6f' User entered '14 Feb 2021 11:19:28'	System	14 Feb 2021 16:19:31
	System	14 Feb 2021 16:19:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-21T08:58:14', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba6506a6-336a-4c51-9cb7-ccf79dafc0c0'	System	21 Feb 2021 13:58:29
User entered 'No (N)'	System	21 Feb 2021 13:58:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-21T08:58:20', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba6506a6-336a-4c51-9cb7-ccf79dafc0c0'	System	21 Feb 2021 13:58:29
User entered 'No (N)'	System	21 Feb 2021 13:58:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-21T08:58:25', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'ba6506a6-336a-4c51-9cb7-ccf79dafc0c0'	System	21 Feb 2021 13:58:29
User entered '21 Feb 2021 08:58:25'	System	21 Feb 2021 13:58:29

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-28T09:16:09-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd969bee6-f15f-4818-a50c-410938aac242'	System	28 Feb 2021 14:16:30
User entered 'No (N)'	System	28 Feb 2021 14:16:30

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-28T09:16:18-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd969bee6-f15f-4818-a50c-410938aac242'	System	28 Feb 2021 14:16:30
User entered 'No (N)'	System	28 Feb 2021 14:16:30

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-28T09:16:26-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'd969bee6-f15f-4818-a50c-410938aac242'	System	28 Feb 2021 14:16:30
User entered '28 Feb 2021 14:16:26'	System	28 Feb 2021 14:16:30

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-08T08:05:08-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e0a6a2f9-a628-4f50-a01b-f0183c687645'	System	08 Mar 2021 13:05:31
User entered 'No (N)'	System	08 Mar 2021 13:05:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-08T08:05:14-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e0a6a2f9-a628-4f50-a01b-f0183c687645'	System	08 Mar 2021 13:05:31
User entered 'No (N)'	System	08 Mar 2021 13:05:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-08T08:05:29-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'e0a6a2f9-a628-4f50-a01b-f0183c687645'	System	08 Mar 2021 13:05:31
User entered '08 Mar 2021 08:05:29'	System	08 Mar 2021 13:05:31

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-14T08:46:08-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c3ec69fb-bfc7-4310-93c3-34afdd07c91e'	System	14 Mar 2021 12:46:28
User entered 'No (N)'	System	14 Mar 2021 12:46:28

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-14T08:46:13-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c3ec69fb-bfc7-4310-93c3-34afdd07c91e'	System	14 Mar 2021 12:46:28
User entered 'No (N)'	System	14 Mar 2021 12:46:28

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-14T08:46:23-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'c3ec69fb-bfc7-4310-93c3-34afdd07c91e'	System	14 Mar 2021 12:46:28
User entered '14 Mar 2021 08:46:23'	System	14 Mar 2021 12:46:28

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-28T00:26:02-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f35d2bf-e0a4-4514-85fc-6846f49a212a'	System	28 Mar 2021 04:27:09
User entered 'Yes (Y)'	System	28 Mar 2021 04:27:09

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

Have you been exposed to someone with 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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-28T00:26:28-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f35d2bf-e0a4-4514-85fc-6846f49a212a'	System	28 Mar 2021 04:27:09
User entered 'No (N)'	System	28 Mar 2021 04:27:09

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-28T00:26:37-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f35d2bf-e0a4-4514-85fc-6846f49a212a'	System	28 Mar 2021 04:27:09
User entered 'No (N)'	System	28 Mar 2021 04:27:09

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[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 (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-28T00:26:53-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f35d2bf-e0a4-4514-85fc-6846f49a212a'	System	28 Mar 2021 04:27:09
User entered 'No (N)'	System	28 Mar 2021 04:27:09

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-03-28T00:27:03-04:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: '9f35d2bf-e0a4-4514-85fc-6846f49a212a' User entered '28 Mar 2021 00:27:03'	System	28 Mar 2021 04:27:09
	System	28 Mar 2021 04:27:09

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:16:32

US3202185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:16:32
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:16:32

US3202185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:23

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 05:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-28T09:16:39-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'cb570bab-faec-4129-8391-3087e4c72091'	System	28 Feb 2021 14:16:48
User entered 'No (N)'	System	28 Feb 2021 14:16:48

US3202185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26BFDB82-BF48-4F90-80D6-6B4AB9396A3C)', Time: '2021-02-28T09:16:45-05:00', User OID: 'PatientReportedOutcome (US3202185)', ODM File OID: 'cb570bab-faec-4129-8391-3087e4c72091'	System	28 Feb 2021 14:16:48
User entered '28 Feb 2021 14:16:45'	System	28 Feb 2021 14:16:48

US3202185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Nov 2020 14:03:30

US3202185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered '06 Nov 2020'	(b) (4) zackery harmon (b) (4)	06 Nov 2020 14:03:30
	(b) (4)	

US3202185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Nov 2020 14:03:30

US3202185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Nov 2020 14:03:30
	(b) (4)	

US3202185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:37
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Nov 2020 14:03:43

US3202185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:08
User entered 'I'	System	06 Nov 2020 14:03:43

US3202185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:29:50

US3202185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:29:50

US3202185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:29:50

US3202185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:29:50

US3202185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:29:54

US3202185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User entered 'I'	System	14 Dec 2020 14:29:54

US3202185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	13 Jan 2021 17:46:10

US3202185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '13 Jan 2021'	Lilian Nukuna (b) (4)	13 Jan 2021 17:46:10

US3202185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4)	13 Jan 2021 17:46:10

US3202185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'left a voice message'	Lilian Nukuna (b) (4)	13 Jan 2021 17:46:10

US3202185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	13 Jan 2021 17:46:17

US3202185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User entered 'I'	System	13 Jan 2021 17:46:17

US3202185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:24

US3202185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:03:37
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	21 Feb 2021 15:55:29
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Feb 2021 15:55:24
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 15:55:24

US3202185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:24

US3202185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:24

US3202185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:34

US3202185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:18
User entered 'I'	System	21 Feb 2021 15:55:34

US3202185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:30

US3202185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 09:41:54
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'noted' (Site from System).	Teresa Deese (b) (4)	29 Mar 2021 18:47:36
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	29 Mar 2021 18:47:30
User entered '29 Mar 2021'	Teresa Deese (b) (4)	29 Mar 2021 18:47:30

US3202185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:30

US3202185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered 'VISIT4'	System	29 Mar 2021 18:47:30

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered empty.	System	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered empty.	System	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered empty.	System	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered empty.	System	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered empty.	System	29 Mar 2021 18:47:48

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38

US3202185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38

US3202185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:54

US3202185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:47:54

US3202185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:48:17

US3202185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '29 Mar 2021'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:48:17

US3202185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '14:23'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:48:17

US3202185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered '29 Mar 2021 14:23'	System	29 Mar 2021 18:48:17

US3202185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 18:48:03

US3202185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:55:38
User entered 'I'	System	29 Mar 2021 18:48:03

US3202185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 12:48:28

US3202185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
	(b) (4)	
User entered '14 Apr 2021'	Lilian Nukuna (b) (4)	14 Apr 2021 12:48:28

US3202185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	14 Apr 2021 12:48:28

US3202185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Apr 2021 12:48:28

US3202185

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 12:48:35

US3202185

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 12:48:35

US3202185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:08

US3202185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:08

US3202185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[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 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:08

US3202185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 18:16:08

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:32

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:32

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Placebo (Placebo)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'I'	System	01 Feb 2021 18:16:23

US3202185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'I'	System	01 Feb 2021 18:16:23

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4)	01 Feb 2021 18:17:37
	Teresa Deese (b) (4)	

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	01 Feb 2021 18:17:37
DataPoint set to visible.	System	01 Feb 2021 18:16:23

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4)	01 Feb 2021 18:17:37
	Teresa Deese (b) (4)	

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	01 Feb 2021 18:17:37
DataPoint set to visible.	System	01 Feb 2021 18:16:23

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 18:17:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 18:17:57
User entered '10:30' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 18:17:57
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 18:17:37
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1 Feb 2021 10:30'	System	01 Feb 2021 18:17:57
User entered empty.	System	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '36.6' C	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '98'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'bpm'	System	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '20'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'breaths/min'	System	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '110'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '79'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:17:37

US3202185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	01 Feb 2021 18:17:37
DataPoint set to visible.	System	01 Feb 2021 18:16:23

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '11:40'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1 Feb 2021 11:40'	System	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 10:44:02
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Teresa Deese (b) (4)	01 Feb 2021 18:18:59
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Feb 2021 18:18:41
User entered '35.1' C	Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '105'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'bpm'	System	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '17'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'breaths/min'	System	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '114'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '73'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:18:41

US3202185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	01 Feb 2021 18:18:41

US3202185

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:06

US3202185

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:06

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mRNA-1273'	System	01 Feb 2021 18:19:21
DataPoint set to visible.	System	01 Feb 2021 18:16:23

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '10:58'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1 Feb 2021 10:58'	System	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'ONCE'	System	01 Feb 2021 18:19:21

US3202185

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

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 18:19:21

US3202185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:36

US3202185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:36

US3202185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '10:55'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:36

US3202185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1 Feb 2021 10:55'	System	01 Feb 2021 18:19:36

US3202185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:52

US3202185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:52

US3202185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '10:51'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:52

US3202185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1 Feb 2021 10:51'	System	01 Feb 2021 18:19:52

US3202185

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

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 18:19:58

US3202185

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

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'I'	System	01 Feb 2021 18:19:58

US3202185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:44

US3202185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:20:12
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	21 Feb 2021 15:55:49
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Feb 2021 15:55:44
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 15:55:44

US3202185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:44

US3202185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:44
	(b) (4)	

US3202185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 15:55:58

US3202185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'I'	System	21 Feb 2021 15:55:58

US3202185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered '1'	System	21 Feb 2021 15:55:58
DataPoint set to visible.	System	21 Feb 2021 15:55:58

US3202185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:49:41

US3202185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:49:41

US3202185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:49:41

US3202185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'OLD29'	System	01 Mar 2021 19:49:41

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '13:05'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered '1 Mar 2021 13:05'	System	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '36.8' C	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '108'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'bpm'	System	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '16'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'breaths/min'	System	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '128'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'mmHg'	System	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '79'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'mmHg'	System	01 Mar 2021 19:51:42

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '14:05'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered '1 Mar 2021 14:05'	System	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '36.9' C	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '94'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'bpm'	System	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '17'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'breaths/min'	System	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '139'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'mmHg'	System	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '93'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'mmHg'	System	01 Mar 2021 19:52:46

US3202185

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:57

US3202185

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:51:57

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'mRNA-1273'	System	01 Mar 2021 19:53:02
DataPoint set to visible.	System	21 Feb 2021 15:55:58

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '1 Mar 2021'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '13:25'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered '1 Mar 2021 13:25'	System	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'ONCE'	System	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 19:53:02

US3202185

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Mar 2021 19:53:08

US3202185

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'I'	System	01 Mar 2021 19:53:08

US3202185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	08 Mar 2021 20:09:58

US3202185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered '8 Mar 2021'	Lilian Nukuna (b) (4)	08 Mar 2021 20:09:58

US3202185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	08 Mar 2021 20:09:58

US3202185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	08 Mar 2021 20:09:58

US3202185

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	08 Mar 2021 20:10:05

US3202185

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:43
User entered 'I'	System	08 Mar 2021 20:10:05

US3202185

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Mar 2021 18:47:10

US3202185

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '29 Mar 2021'	Teresa Deese (b) (4)	29 Mar 2021 18:47:10

US3202185

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	29 Mar 2021 18:47:10

US3202185

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	29 Mar 2021 18:47:10

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 18:47:00

US3202185

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	29 Mar 2021 18:46:52

US3202185

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	29 Mar 2021 18:46:52

US3202185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	29 Mar 2021 18:46:38

US3202185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '29 Mar 2021'	Teresa Deese (b) (4)	29 Mar 2021 18:46:38

US3202185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '14:23'	Teresa Deese (b) (4)	29 Mar 2021 18:46:38

US3202185

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 14:23'	System	29 Mar 2021 18:46:38

US3202185

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:40:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:41
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 152, 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)	16 Apr 2021 10:37:59
Signature has been broken.	Teresa Deese (b) (4)	13 Apr 2021 14:26:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 14:26:41
Query 'Per DM CLR: Per Safety Follow-up Diary Day 152, 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 'no AE. reg appt' (Site from DM).	Teresa Deese (b) (4)	07 Apr 2021 15:49:36
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, 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)	02 Apr 2021 17:13:59

US3202185

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:40:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:32:53
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'exposed to someone w covid. got tested. no sx' (Site from DM).	Teresa Deese (b) (4)	29 Mar 2021 20:35:43
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:10:41
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:09:09
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:17

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:35
User entered 'USA-US128-2021-mRNA-1273-P301000019'	System	14 Apr 2021 15:41:30
User entered 'New'	(b) (4), (b) (6)	14 Apr 2021 15:41:30

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 20:46:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 14:45:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 14:45:48
Data point term sent to Coder	System	13 Apr 2021 14:34:02
User entered 'weakness'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '6 Apr 2021'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:12
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:21:09
Signature has been broken.	Erica Osmundsen (b) (4)	21 Apr 2021 18:21:09
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 18:21:09
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:20:21
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:12
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:07:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:22:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Apr 2021 18:22:20
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED BASED ON SUBJECT'S REPORT--STILL NO RECORDS RECEIVED TO DATE' (Site from Safety).	Erica Osmundsen (b) (4)	21 Apr 2021 18:21:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Apr 2021 18:20:21
Signature has been broken.	Erica Osmundsen (b) (4)	21 Apr 2021 18:20:21
User entered '13 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 18:20:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:44:57
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
User entered empty.	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4)	13 Apr 2021 14:33:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	13 Apr 2021 14:33:54
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	13 Apr 2021 14:32:58
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'I'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '6 Apr 2021'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '13 Apr 2021'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered 'I'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:12
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:07:25
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPDATED' (Site from Safety).	Erica Osmundsen (b) (4)	21 Apr 2021 18:23:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 18:22:20
Signature has been broken.	Erica Osmundsen (b) (4)	21 Apr 2021 18:21:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 18:21:09
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:45:18
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
User entered 'Unknown (UNKNOWN)'	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	28 Apr 2021 20:46:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 20:45:56
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).	(b) (4), (b) (6)	22 Apr 2021 17:07:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:07:42
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:07:33

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[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 'NOT YET KNOWN' (Site from Safety).	Erica Osmundsen (b) (4)	21 Apr 2021 18:26:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'NO RECORDS RECEIVED TO DATE' (Site from Safety).	Erica Osmundsen (b) (4)	21 Apr 2021 18:25:50
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'SUBJECT SAID NO COVID-19 TESTING DONE. STILL NO RECORDS RECEIVED--HAVE REQUESTED AGAIN' (Site from Safety).	Erica Osmundsen (b) (4)	21 Apr 2021 18:25:27
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).	(b) (4), (b) (6)	21 Apr 2021 14:45:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:45:28

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:44:38
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:53
User entered 'subj stated saw hepatologist for Xplant w/u. Sent to oncology to R/O any cancer. Oncologist sent subj to hospital for c/o weakness & testing. records from hepatologist & hospital have been requested.'	(b) (4) Teresa Deese (b) (4)	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 14:33:54
User entered '0'	System	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:32:58

US3202185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:40:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 14:32:58

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Per CDM: Prior/Concomitant Medication and Vaccination Summary noted as "Yes" however Prior/Concomitant Medications page is not updated. Please review and update accordingly else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 10:28:21
Query 'Per CDM: Prior/Concomitant Medication and Vaccination Summary noted as "Yes" however Prior/Concomitant Medications page is not updated. Please review and update accordingly else clarify' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	05 Oct 2020 17:31:26
User opened query 'Per CDM: Prior/Concomitant Medication and Vaccination Summary noted as "Yes" however Prior/Concomitant Medications page is not updated. Please review and update accordingly else clarify' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:40:42
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:04:24

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 08:00:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 08:00:33
Data point term sent to Coder	System	05 Oct 2020 17:21:39
User entered 'SPIRONOLACTONE'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'BILATERAL EDEMA LEGS'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '100'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

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

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:20:43

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:22:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:22:31
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 17:21:39
User entered 'TRAZODONE'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '50'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:21:26

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: RIFAXIMIN, PRODUCTSYNONYM: XIFAXAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 17:35:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:35:41
Data point term sent to Coder	System	16 Dec 2020 18:33:58
Coding entries removed.	(b) (4), (b) (6)	16 Dec 2020 18:33:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: RIFAXIMIN, PRODUCTSYNONYM: XIFAXAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 07:53:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 07:53:39
Data point term sent to Coder	System	05 Oct 2020 17:22:41
User entered 'XIFAXAN'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User closed query 'Per CDM: Please verify if this pertains to #9 HYPERAMMONEMIA in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record? Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:42:02
Query 'Per CDM: Please verify if this pertains to #9 HYPERAMMONEMIA in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record? Please review and reconcile Con Med and MH as appropriate else clarify.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 18:37:53
User entered 'HIGH BLOOD AMMONIA LEVEL/HYPERAMMONEMIA' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 18:33:52
User opened query 'Per CDM: Please verify if this pertains to #9 HYPERAMMONEMIA in the Medical History eCRF? If yes, note that Con Med 'indication' does not match the corresponding MH record? Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:02:42
User entered 'HIGH BLOOD AMMONIA LEVEL'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '550'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:22:38

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 17:26:19
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 Oct 2020 17:26:19
Data point term sent to Coder	System	05 Oct 2020 17:24:49
User entered 'ALLOPURINOL'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'GOUT'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '100'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2011'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:23:50

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:26:20
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 Oct 2020 17:26:20
Data point term sent to Coder	System	05 Oct 2020 17:24:50
User entered 'CITALOPRAM'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'DEPRESSION'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '40'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:24:23

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 17:27:26
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 Oct 2020 17:27:26
Data point term sent to Coder	System	05 Oct 2020 17:25:53
User entered 'FINASTERIDE'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'HAIR LOSS'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '2.5'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '17 Mar 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:25:36

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 23:35:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:35:18
Data point term sent to Coder	System	05 Oct 2020 17:26:55
User entered 'FOLIC ACID'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'FOLIC ACID DEFICIENCY'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '1'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:26:06

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 23:36:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 23:36:19
Data point term sent to Coder	System	05 Oct 2020 17:27:58
User entered 'FUROSEMIDE'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'BILATERAL EDEMA LEGS'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '20'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '25 Apr 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:27:12

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 09:00:18
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 Oct 2020 09:00:18
Data point term sent to Coder	System	05 Oct 2020 17:27:58
User entered 'POTASSIUM CL'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'POTASSIUM DEFICIENCY'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '10'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'UN UNK 2020'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:40:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:27:51

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:40:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 20:30:40
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:04:31

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:23

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered '4 Jan 2021'	Teresa Deese (b) (4)	01 Feb 2021 20:31:20

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'paracentesis'	Teresa Deese (b) (4)	01 Feb 2021 20:31:20

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered 'Medical History (MH)'	Teresa Deese (b) (4)	01 Feb 2021 20:31:20

US3202185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:40:23

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:36
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 20:31:20

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'USA-US128-2021-MRNA-1273-P301000019'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Mark'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'McKenzie'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:10:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
User entered 'US'	(b) (4) System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 17:10:43
User entered '1'	System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'USA-US128-2021-MRNA-1273-P301000019'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Mark'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'McKenzie'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:10:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
User entered 'US'	(b) (4) System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 17:10:43
User entered '1'	System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
User entered '14/Apr/2021 10:42'	(b) (4) System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:10:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'USA-US128-2021-MRNA-1273-P301000019'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Yes (Y)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'No (N)'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'Mark'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:41:54
User entered 'McKenzie'	System	14 Apr 2021 15:41:30

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 17:10:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:58
User entered 'US'	(b) (4) System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 17:10:43
User entered '1'	System	14 Apr 2021 15:42:02

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:40:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:12
User entered '22/Apr/2021 13:10'	(b) (4) System	22 Apr 2021 17:10:43

US3202185

Folder: SAE USA-US128-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:40:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:10:43