

US3622197 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:15:34

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US3622197

Form: Participant Creation

Data signed: (b) (4) 26 Sep 2020 13:10:41

Generated On: 10 Jun 2021 09:15:34

[Participant ID](#)

US3622197

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

US3622197

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3622197

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Sep 2020 13:10:41

Generated On: 10 Jun 2021 09:15:34

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3622197

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Sep 2020 13:10:42

Generated On: 10 Jun 2021 09:15:34

Date of Informed Consent (dd MMM yyyy) 17 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

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

Was participant enrolled in the study? Yes ☒
No ☐

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

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

If Yes, previous participant number _____
Enrollment Trigger 1

US3622197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Sep 2020 13:10:42

Generated On: 10 Jun 2021 09:15:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3622197

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Were any significant conditions reported?

Yes ☒

No ☐

US3622197

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3622197

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	SEVERE OBESITY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622197

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622197

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622197

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	PARTIAL HYSTEROTOMY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	ABNORMAL VIRGINIAL BLEEDING
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3622197

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	SCIATICA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622197

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622197

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	GI BLEED
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3622197

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	BILATERAL FOOT TENDONITIS
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3622197

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	GALL STONES
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3622197

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Condition	ABDOMINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3622197

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:25
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	253.0 lb
BMI (<i>xxx.x</i>)	42.18943 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
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)	

US3622197

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Date of assessment (dd MMM yyyy) 17 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2008

Date of surgery unknown False

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

Date of last menstruation unknown False

US3622197

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

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

SOCIALY ACTIVE -
CUSTOMER SERVICE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 13:10:42

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 146526

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) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Height	ND - Not Done
Weight	ND - Not Done

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:25
Temperature (xxx.x)	99.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:01
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	THERMAL SCANNER
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3622197

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

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.

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Sep 2020 13:10:42

Generated On: 10 Jun 2021 09:15:34

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) 17 SEP 2020

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

Treatment Date and Time (derived) 17 SEP 2020 13:24

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

US3622197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

17 SEP 2020 11:40

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	17 SEP 2020 11:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:48:43

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

97.5 °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

17 SEP 2020 14:03

PC Open Date & Time

17 SEP 2020 13:44

PC Close Date & Time

17 SEP 2020 16:14

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	17 SEP 2020 20:34
PC Open Date & Time	17 SEP 2020 17:09
PC Close Date & Time	18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:04

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

19 SEP 2020 20:25

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

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

20 SEP 2020 20:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp 21 SEP 2020 20:15

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:16

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

17 SEP 2020 14:04

PC Open Date & Time

17 SEP 2020 13:44

PC Close Date & Time

17 SEP 2020 16:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

17 SEP 2020 20:35

PC Open Date & Time

17 SEP 2020 17:09

PC Close Date & Time

18 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

18 SEP 2020 20:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

19 SEP 2020 20:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

20 SEP 2020 20:23

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

21 SEP 2020 20:16

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

22 SEP 2020 20:16

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

23 SEP 2020 20:18

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 14:05
PC Open Date & Time	17 SEP 2020 13:44
PC Close Date & Time	17 SEP 2020 16:14

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 20:36
PC Open Date & Time	17 SEP 2020 17:09
PC Close Date & Time	18 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2121

EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	18 SEP 2020 20:09
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2121

EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	19 SEP 2020 20:28
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	20 SEP 2020 20:24
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	21 SEP 2020 20:16
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2121

EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	22 SEP 2020 20:17
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

66 of 2121

EAB) (1725)

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	23 SEP 2020 20:19
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3622197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:05:15

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments
If Contact Not Made, please provide Comments
UNABLE TO CONTACT;
MULTIPLE ATTEMPTS MADE
AND MESSAGES LEFT

US3622197

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:05:15

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 18:05:15

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments UNABLE TO CONTACT;
MESSAGE LEFT

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 18:05:15

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Oct 2020 20:08:13

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Oct 2020 20:08:13

Generated On: 10 Jun 2021 09:15:34

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 10:53
Temperature (xxx.x)	99.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Oct 2020 20:08:13

Generated On: 10 Jun 2021 09:15:34

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:44
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3622197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Oct 2020 20:08:13

Generated On: 10 Jun 2021 09:15:34

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.

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 12:13

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

US3622197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	11:05 (24 HR)
Collection date and time (derived)	15 OCT 2020 11:05

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	15 OCT 2020 11:15
Nasopharyngeal Swab 2	No		

US3622197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

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

15 OCT 2020 12:33

PC Close Date & Time

15 OCT 2020 15:03

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	15 OCT 2020 21:24
PC Open Date & Time	15 OCT 2020 15:58
PC Close Date & Time	16 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

16 OCT 2020 21:18

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

17 OCT 2020 21:12

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 20:44

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 21:08

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

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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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

20 OCT 2020 21:12

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

21 OCT 2020 20:58

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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 ☐

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.**

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

PC Open Date & Time

15 OCT 2020 12:33

PC Close Date & Time

15 OCT 2020 15:03

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

15 OCT 2020 21:22

PC Open Date & Time

15 OCT 2020 15:58

PC Close Date & Time

16 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 21:16

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 21:13

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

18 OCT 2020 20:45

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

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 OCT 2020 21:09

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:13

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 20:58

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 OCT 2020 12:33

PC Close Date & Time

15 OCT 2020 15:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 21:23
PC Open Date & Time	15 OCT 2020 15:58
PC Close Date & Time	16 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	16 OCT 2020 21:18
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

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)

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	17 OCT 2020 21:13
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	18 OCT 2020 20:46
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

EAB) (1725)

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US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	19 OCT 2020 21:10
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	20 OCT 2020 21:13
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

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EAB) (1725)

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

Yes ☐	
PC Time stamp	21 OCT 2020 20:59
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3622197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 15:03:38

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:03:38

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:36:20

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:36:20

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:36:30

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:36:30

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Nov 2020 19:06:18

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Nov 2020 19:06:18

Generated On: 10 Jun 2021 09:15:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:45
Temperature (xxx.x)	99.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Nov 2020 19:06:18

Generated On: 10 Jun 2021 09:15:34

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.

US3622197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Nov 2020 19:06:18

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

12 NOV 2020 11:00

US3622197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 19:06:18

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 14:34:45
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:55:48
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 JAN 2021 22:29:26
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 10:27:07
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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	24 JAN 2021 14:09:18
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

02 FEB 2021 08:54:18

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 15:18:20
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:26:51

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 12:04:36

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 17:52:30

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

08 MAR 2021 12:31:02

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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	15 MAR 2021 09:35:27
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 17:03:29

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 13:32:29

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

05 APR 2021 19:36:28

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

10 APR 2021 12:21:27

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

18 APR 2021 09:52:14

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 23:06:13

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 264

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

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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°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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 411

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

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

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

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

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

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

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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09 FEB 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

Date and time of submission

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12 FEB 2022 00:01

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16 FEB 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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26 FEB 2022 00:01

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02 MAR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

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US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

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US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

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US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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26 MAR 2022 00:01

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30 MAR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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13 APR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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23 APR 2022 00:01

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27 APR 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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07 MAY 2022 00:01

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11 MAY 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 621

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

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

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

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

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

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

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 691

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

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

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

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

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

Fever (Temperature $\geq$ 100.4°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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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07 SEP 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

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17 SEP 2022 00:01

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21 SEP 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

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24 SEP 2022 00:01

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28 SEP 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

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05 OCT 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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12 OCT 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

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02 NOV 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

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09 NOV 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

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16 NOV 2022 23:59

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3622197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:15:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 17:52:54

US3622197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO CONTACT;
MESSAGES LEFT

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 14:04:48

Generated On: 10 Jun 2021 09:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622197

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 14:04:48

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT4

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	8 APR 2021
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 10:40
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
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)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

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.

US3622197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	8 APR 2021 11:10

US3622197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622197

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:15:34

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3622197

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:15:34

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622197

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	28 JAN 2021

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

Folder OID	UNBLND_DECIDE

US3622197

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:15:03

Generated On: 10 Jun 2021 09:15:34

Date of updated informed consent (dd MMM yyyy) 28 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3622197

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	10:05 (24 HR)
Collection date and time (derived)	28 JAN 2021 10:05

US3622197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	10:00
Collection Date and Time (derived)	28 JAN 2021 10:00

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Mar 2021 21:58:13

Generated On: 10 Jun 2021 09:15:34

Visit Date	25 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:58:13

Generated On: 10 Jun 2021 09:15:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3622197

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Jan 2021 15:08:16

Generated On: 10 Jun 2021 09:15:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

AEID USA-US085-2021-MRNA-1273-P30
1000002

Adverse event WORSENING ANEMIA

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

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

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

Start date (dd MMM yyyy) 12 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 15 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 12 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 15 JAN 2021

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

PARTICIPANT REPORTED
DURING MONTH 4 SAFETY
CALL THAT THEY WERE
HOSPITALIZED DUE TO
ANEMIA.

UPDATE: THE PARTICIPANT
WAS ADMITTED IN THE
HOSPITAL FROM 01/12/2021
THROUGH 01/15/2021. SHE
WENT TO THE ER WITH
COMPLAINTS OF SHORTNESS
OF BREATH, FATIGUE, AND
WEAKNESS. LABS ON 01/12/2021
REVEALED A HEMOGLOBIN OF
5.2, RBC 2.7, HEMATOCRIT 20.8,
MCV 76.8, MCH 19.2 MCHC 25,
RDW-CV 18.5, IRON 17, TIBC 495,
AND IRON SATURATION 3.
FOBT WAS NEGATIVE AND
COVID TEST ON 01/12/2021 WAS
NEGATIVE. CHEST X-RAY ON
01/12/2021 WAS WITHOUT
ACUTE PATHOLOGY AND EKG
WITH NSR. THE PARTICIPANT
RECEIVED 2 UNITS OF PRBC'S
ON 01/13/2021 AND 1 UNIT OF
PRBC'S ON 01/15/2021. SHE WAS
DISCHARGED ON 01/15/2021 IN
STABLE CONDITION WITH A
HEMOGLOBIN OF 8.6. WHILE
ADMITTED SHE RECEIVED
VENOFIR 200MG IV DAILY, B12
1,000MCG IM DAILY, ATIVAN
1MG FOR INSOMNIA ONCE ON

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

01/13/2021, PROTONIX 40 MG PO
DAILY, NORVASC 5MG PO
DAILY, AND IV FLUIDS. SHE
HAS A KNOWN HISTORY OF
MICROCYTIC IRON
DEFICIENCY ANEMIA WITH A
GI BLEED IN JUNE 2020 PER
MEDICAL RECORDS.
ADDITIONAL HISTORY PER
MEDICAL RECORDS INCLUDES
COPD, DEPRESSION, HTN,
MIGRAINE, SCIATICA,
BILATERAL FOOT TENDONITIS,
CHRONIC BRONCHITIS, AND
INSOMNIA.

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

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

AEID

Adverse event

BILATERAL RIBCAGE PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 16:12:44

Generated On: 10 Jun 2021 09:15:34

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

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Oct 2020 20:08:12

Generated On: 10 Jun 2021 09:15:34

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

Yes ☒

No ☐

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

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS SUPPLEMENT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 1 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication	VITAMIN D
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS SUPPLEMENT
Dose per administration	50000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☒ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☒ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication PROTONIX

Prophylaxis Yes ☒
No ☐

Indication PREVENT GERD

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication VENOFIR

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 13 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication TYLENOL

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF FEVER

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 15 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIB CAGE PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 24 FEB 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

Name of Medication 0.9% NACL

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 CONTINUOUS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:56:59

Generated On: 10 Jun 2021 09:15:34

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 21:58:12

Generated On: 10 Jun 2021 09:15:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 JAN 2021	CHEST X-RAY	Diagnostic	
12 JAN 2021	EKG	Diagnostic	
13 JAN 2021	BLOOD TRANSFUSION (2 UNITS OF PRBS'S)	Adverse Event	
15 JAN 2021	BLOOD TRANSFUSION (1 UNIT OF PRBC)	Adverse Event	
12 JAN 2021	CBC LAB	Diagnostic	
12 JAN 2021	FOBT	Diagnostic	
12 JAN 2021	IRON LAB	Diagnostic	
12 JAN 2021	TIBC LAB	Diagnostic	
12 JAN 2021	IRON SATURATION LAB	Diagnostic	

US3622197

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:15:34

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 ☐

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

SAEID	USA-US085-2021-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

SAEID	USA-US085-2021-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/JAN/2021 23:39
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

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 14:07:03

Generated On: 10 Jun 2021 09:15:34

SAEID	USA-US085-2021-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/JAN/2021 10:39
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

US3622197 (Prod: University of Miami)

US3622197

Form: Participant Creation

Generated On: 10 Jun 2021 09:15:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'US3622197'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:34

US3622197

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:43:53
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:33:07
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:10:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:27:38

US3622197

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:35

US3622197

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[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 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:27:38

US3622197

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'SCRN'	System	17 Sep 2020 17:27:38

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:36

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '56'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'YEARS'	System	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '56'	System	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '1'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:15:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:31

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Sep 2020'	System	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:11

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:49:35

US3622197

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:15:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '1'	System	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:15:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:08:04

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	30 Sep 2020 13:37:49
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	30 Sep 2020 13:37:49
Data point term sent to Coders System	System	30 Sep 2020 13:37:00
User entered 'Hypertension'	(b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
Signature has been broken.	(b) (4) Junlin Long (b) (4)	24 Nov 2020 13:36:32
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 1990'	System	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '1990'	System	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:36:18

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Sep 2020 13:38:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:38:57
Data point term sent to Coder	System	30 Sep 2020 13:38:01
User entered 'Severe Obesity'	(b) (4), (b) (6)	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 13:37:25
	(b) (4), (b) (6)	

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2015'	System	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2015'	System	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:37:25

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	(b) (4) Coder Import	30 Sep 2020 13:39:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import	30 Sep 2020 13:39:47
Data point term sent to Coder	System	30 Sep 2020 13:39:04
User entered 'Anemia'	(b) (4), (b) (6)	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 13:38:04
	(b) (4), (b) (6)	

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2016'	System	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2016'	System	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	30 Sep 2020 13:38:04

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 17:30:57
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:31:07
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User closed query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:20:31
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:44:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:44:25
Query 'Per MM, please expand the abbreviation' answered with 'condition updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	19 Oct 2020 16:43:47
Data point term sent to Coder	System	19 Oct 2020 16:43:46
Coding entries removed.	Junlin Long (b) (4) (b) (4)	19 Oct 2020 16:43:33
Signature has been broken.	Junlin Long (b) (4) (b) (4)	19 Oct 2020 16:43:33
User entered 'Chronic obstructive pulmonary disease' reason for change: New Information	Junlin Long (b) (4) (b) (4)	19 Oct 2020 16:43:33
User opened query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:00:42
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	08 Oct 2020 13:48:43

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:27:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 16:27:50
Data point term sent to Coder	System	02 Oct 2020 16:26:35
User entered 'COPD'	(b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2010'	System	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2010'	System	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	02 Oct 2020 16:25:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF if applicable. Please verify and update as appropriate or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF if applicable. Please verify and update as appropriate or clarify. ' answered with 'mh updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	28 Jan 2021 16:03:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF if applicable. Please verify and update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:12:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterotomy, LLT: Hysterotomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 19:53:09
Data point term sent to Coder	System	23 Nov 2020 17:47:33
User entered 'partial hysterotomy'	Junlin Long (b) (4) (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'un UNK 2008'	Junlin Long (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)'	Junlin Long (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'un UNK 2008'	Junlin Long (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long (b) (4)	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2008'	System	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2008'	System	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2008'	System	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2008'	System	23 Nov 2020 17:46:40

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal disorders NEC, PT: Vaginal haemorrhage, LLT: Vaginal bleeding - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:33:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 13:33:55
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 14:07:03
Data point term sent to Coder	System	28 Jan 2021 16:03:02
User entered 'abnormal virginial bleeding'	Junlin Long (b) (4) (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4) (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4) (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'un UNK 2008'	Junlin Long (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)'	Junlin Long (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'un UNK 2008'	Junlin Long (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long (b) (4)	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2008'	System	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2008'	System	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2008'	System	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2008'	System	28 Jan 2021 16:02:55
DataPoint activated with code reason code Data required.	Junlin Long (b) (4)	28 Jan 2021 15:58:27
DataPoint inactivated with code reason code Data not required.	Junlin Long (b) (4)	24 Nov 2020 13:36:32

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
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.	(b) (4)	28 Jan 2021 16:05:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 16:05:20
Data point term sent to Coder	(b) (4)	28 Jan 2021 16:04:03
User entered 'insomnia'	System	28 Jan 2021 16:03:36
	Junlin Long (b) (4)	
	(b) (4)	

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'un UNK 2017'	Junlin Long (b) (4)	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	Junlin Long (b) (4)	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long (b) (4)	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2017'	System	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2017'	System	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	28 Jan 2021 16:03:36

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:58
Data point term sent to Coder	System	03 Mar 2021 14:01:39
User entered 'sciatica'	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un UNK 2010'	Junlin Long (b) (4)	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	Junlin Long (b) (4)	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long (b) (4)	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2010'	System	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2010'	System	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:00:41

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:59
Data point term sent to Coder	System	03 Mar 2021 14:01:39
User entered 'depression'	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un UNK 2013'	Junlin Long (b) (4)	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	Junlin Long (b) (4)	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2013'	System	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2013'	System	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:01:04

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:02:58
Data point term sent to Coder	System	03 Mar 2021 14:01:39
User entered 'migraine'	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un UNK 2018'	Junlin Long (b) (4)	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2018'	System	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2018'	System	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	03 Mar 2021 14:01:30

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 14:03:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:03:57
Data point term sent to Coder	System	03 Mar 2021 14:02:40
User entered 'GI bleed'	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un Jun 2020'	Junlin Long	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long (b) (4)	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	03 Mar 2021 14:02:48
User entered 'UN Jun 2020' reason for change: Per Query Resolution	System	03 Mar 2021 14:02:48
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Junlin Long (b) (4)	03 Mar 2021 14:02:25
User entered 'un UNK 2020'	(b) (4)	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jun 2020'	System	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jun 2020'	System	03 Mar 2021 14:02:48
User entered 'Jan 2020'	System	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	03 Mar 2021 14:02:25

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendonitis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	04 Mar 2021 13:31:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 13:31:58
Data point term sent to Coder	System	03 Mar 2021 14:04:44
User entered 'bilateral foot tendonitis'	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long (b) (4)	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2020'	System	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2020'	System	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	03 Mar 2021 14:04:05

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 12:13:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 12:13:28
Data point term sent to Coder	System	07 Apr 2021 12:12:36
User entered 'gall stones'	(b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2016'	System	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2016'	System	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	07 Apr 2021 12:12:29

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 12:19:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 12:19:30
Data point term sent to Coder	System	07 Apr 2021 12:18:41
User entered 'abdominal hernia'	(b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'Jan 2020'	System	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '2020'	System	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	07 Apr 2021 12:18:07

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '11:25'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '17 Sep 2020 11:25'	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '65.0' in	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:50:11
DataPoint set to visible.	System	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '253.0' lb	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:50:11
DataPoint set to visible.	System	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '42.18943'	System	30 Sep 2020 12:50:11
DataPoint set to visible.	System	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'kg/m2'	System	30 Sep 2020 12:50:11
DataPoint set to visible.	System	17 Sep 2020 17:28:22

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 13:28:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 12:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 12:52:55
User entered '99.4' F	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:28:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:54
User entered missing code ND - Not Done; reason for change Data Entry Error	System	30 Sep 2020 13:28:54
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User entered empty.	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 13:28:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 12:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 12:52:55
User entered '80'	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'bpm'	System	30 Sep 2020 13:28:40
User entered empty.	System	30 Sep 2020 12:52:55
User entered 'bpm'	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 13:28:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 12:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 12:52:55
User entered '16'	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'breaths/min'	System	30 Sep 2020 13:28:40
User entered empty.	System	30 Sep 2020 12:52:55
User entered 'breaths/min'	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 13:28:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 12:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 12:52:55
User entered '142'	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'mmHg'	System	30 Sep 2020 13:28:40
User entered empty.	System	30 Sep 2020 12:52:55
User entered 'mmHg'	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Sep 2020 13:28:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 13:28:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:28:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 12:52:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 12:52:55
User entered '85'	(b) (4), (b) (6)	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'mmHg'	System	30 Sep 2020 13:28:40
User entered empty.	System	30 Sep 2020 12:52:55
User entered 'mmHg'	System	30 Sep 2020 12:50:11

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41

US3622197

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41

US3622197

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:52

US3622197

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:26:52

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User closed query 'Per DM CLR: Please review Post-Menopausal as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:41:12
Query 'Per DM CLR: Please review Post-Menopausal as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'reason corrected and recorded in mh' (Site from DM).	Junlin Long (b) (4) (b) (4)	24 Nov 2020 13:36:59
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Nov 2020 13:36:07
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	24 Nov 2020 13:36:07
User opened query 'Per DM CLR: Please review Post-Menopausal as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 13:07:29
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:56:11
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Signature has been broken.	Junlin Long (b) (4)	24 Nov 2020 13:36:07
User entered 'un UNK 2008' reason for change: New Information	Junlin Long (b) (4)	24 Nov 2020 13:36:07
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 18:56:11
User entered 'UN UNK 2008'	(b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	24 Nov 2020 13:36:07
User entered empty; reason for change Data Entry Error	(b) (4)	
	Junlin Long (b) (4)	24 Nov 2020 13:36:07
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'UN UNK 2008' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 18:56:11
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:15:34

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 18:54:08

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Socially active - customer service'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:49:12

US3622197

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:15:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 13:49:12
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:29:32

US3622197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:29:32

US3622197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:29:32

US3622197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'VISIT1'	System	17 Sep 2020 17:29:32

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:54:19

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '146526'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:54:19

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:54:19

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:55:57

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 13:56:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 13:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:56:17
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 13:55:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:57

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:55:57

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 13:56:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 13:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:56:17
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 13:55:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:57

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 13:56:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 13:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:56:17
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 13:55:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:57

US3622197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 13:56:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 13:56:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 13:56:17
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 13:55:57
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 13:55:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:26:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:25:59

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '11:25'	(b) (4)	30 Sep 2020 14:01:40
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '17 Sep 2020 11:25'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '99.4' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 14:01:40
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '80'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'bpm'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'breaths/min'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '142'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '85'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:15:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '14:01'	(b) (4)	30 Sep 2020 14:01:40
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '17 Sep 2020 14:01'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'THERMAL SCANNER'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'bpm'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '18'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'breaths/min'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '137'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '84'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	30 Sep 2020 14:01:40

US3622197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'No (N)'	(b) (4)	30 Sep 2020 14:02:13
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 14:02:13
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered '13:24'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '17 Sep 2020 13:24'	System	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:10:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'ONCE'	System	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 17:30:30

US3622197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:04:29

US3622197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:04:29

US3622197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '11:40'	(b) (4)	30 Sep 2020 14:04:29
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '17 Sep 2020 11:40'	System	30 Sep 2020 14:04:29

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered '11:45'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '17 Sep 2020 11:45'	System	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Sep 2020 14:16:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 14:16:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:16:41
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 14:05:16
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered empty.	(b) (4)	30 Sep 2020 14:05:16
	(b) (4), (b) (6)	

US3622197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered empty.	System	30 Sep 2020 14:05:16

US3622197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:48:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:06:55

US3622197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	30 Sep 2020 14:06:55

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:02:48', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '93ec2241-7c22-4f1f-a4bc-d90b7312baf7'	System	17 Sep 2020 18:03:22
User entered 'Yes (Y)'	System	17 Sep 2020 18:03:22

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:03:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '93ec2241-7c22-4f1f-a4bc-d90b7312baf7'	System	17 Sep 2020 18:03:22
User entered '97.5'	System	17 Sep 2020 18:03:22

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:03:10', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '93ec2241-7c22-4f1f-a4bc-d90b7312baf7'	System	17 Sep 2020 18:03:22
User entered 'No (N)'	System	17 Sep 2020 18:03:22

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:03:19', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '93ec2241-7c22-4f1f-a4bc-d90b7312baf7'	System	17 Sep 2020 18:03:22
User entered '17 Sep 2020 14:03'	System	17 Sep 2020 18:03:22

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 13:44'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 16:14'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:33:53', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6921f5ab-931c-42aa-848e-2299a83f0f94'	System	18 Sep 2020 00:34:20
User entered 'Yes (Y)'	System	18 Sep 2020 00:34:20

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6921f5ab-931c-42aa-848e-2299a83f0f94'	System	18 Sep 2020 00:34:20
User entered '97.9'	System	18 Sep 2020 00:34:20

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:09', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6921f5ab-931c-42aa-848e-2299a83f0f94'	System	18 Sep 2020 00:34:20
User entered 'No (N)'	System	18 Sep 2020 00:34:20

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6921f5ab-931c-42aa-848e-2299a83f0f94'	System	18 Sep 2020 00:34:20
User entered '17 Sep 2020 20:34'	System	18 Sep 2020 00:34:20

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 17:09'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 2'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:03:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '197cb839-4de7-49be-a165-d5d727619327'	System	19 Sep 2020 00:04:34
User entered 'Yes (Y)'	System	19 Sep 2020 00:04:34

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:04:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '197cb839-4de7-49be-a165-d5d727619327'	System	19 Sep 2020 00:04:34
User entered '97.0'	System	19 Sep 2020 00:04:34

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:04:22', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '197cb839-4de7-49be-a165-d5d727619327'	System	19 Sep 2020 00:04:34
User entered 'No (N)'	System	19 Sep 2020 00:04:34

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:04:32', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '197cb839-4de7-49be-a165-d5d727619327'	System	19 Sep 2020 00:04:34
User entered '18 Sep 2020 20:04'	System	19 Sep 2020 00:04:34

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 3'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:25:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3b33f4bc-5d66-44d4-aa22-92ddc2bb0edc'	System	20 Sep 2020 00:25:53
User entered 'Yes (Y)'	System	20 Sep 2020 00:25:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:25:37', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3b33f4bc-5d66-44d4-aa22-92ddc2bb0edc'	System	20 Sep 2020 00:25:53
User entered '98.5'	System	20 Sep 2020 00:25:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:25:41', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3b33f4bc-5d66-44d4-aa22-92ddc2bb0edc'	System	20 Sep 2020 00:25:53
User entered 'No (N)'	System	20 Sep 2020 00:25:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:25:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3b33f4bc-5d66-44d4-aa22-92ddc2bb0edc'	System	20 Sep 2020 00:25:53
User entered '19 Sep 2020 20:25'	System	20 Sep 2020 00:25:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 4'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:22:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5ad3221f-61da-4e19-90ad-206763e7aaf5'	System	21 Sep 2020 00:22:53
User entered 'Yes (Y)'	System	21 Sep 2020 00:22:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:22:41', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5ad3221f-61da-4e19-90ad-206763e7aaf5'	System	21 Sep 2020 00:22:53
User entered '98.2'	System	21 Sep 2020 00:22:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:22:38', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5ad3221f-61da-4e19-90ad-206763e7aaf5'	System	21 Sep 2020 00:22:53
User entered 'No (N)'	System	21 Sep 2020 00:22:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:22:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5ad3221f-61da-4e19-90ad-206763e7aaf5'	System	21 Sep 2020 00:22:53
User entered '20 Sep 2020 20:22'	System	21 Sep 2020 00:22:53

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 5'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:15:23', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d8ab285-9490-4b56-93ab-870bf9339cc0'	System	22 Sep 2020 00:15:41
User entered 'Yes (Y)'	System	22 Sep 2020 00:15:41

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:15:31', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d8ab285-9490-4b56-93ab-870bf9339cc0'	System	22 Sep 2020 00:15:41
User entered '97.0'	System	22 Sep 2020 00:15:41

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:15:35', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d8ab285-9490-4b56-93ab-870bf9339cc0'	System	22 Sep 2020 00:15:41
User entered 'No (N)'	System	22 Sep 2020 00:15:41

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:15:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d8ab285-9490-4b56-93ab-870bf9339cc0'	System	22 Sep 2020 00:15:41
User entered '21 Sep 2020 20:15'	System	22 Sep 2020 00:15:41

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 6'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:15:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '421c0aaa-610e-40c8-8923-94dd1dd02361'	System	23 Sep 2020 00:16:08
User entered 'Yes (Y)'	System	23 Sep 2020 00:16:08

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:15:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '421c0aaa-610e-40c8-8923-94dd1dd02361'	System	23 Sep 2020 00:16:08
User entered '98.6'	System	23 Sep 2020 00:16:08

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:15:57', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '421c0aaa-610e-40c8-8923-94dd1dd02361'	System	23 Sep 2020 00:16:08
User entered 'No (N)'	System	23 Sep 2020 00:16:08

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:05', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '421c0aaa-610e-40c8-8923-94dd1dd02361'	System	23 Sep 2020 00:16:08
User entered '22 Sep 2020 20:16'	System	23 Sep 2020 00:16:08

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 7'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:16:19', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '607b3149-51c0-440d-a58a-79f15830b6c9'	System	24 Sep 2020 00:17:33
User entered 'Yes (Y)'	System	24 Sep 2020 00:17:33

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:17:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '607b3149-51c0-440d-a58a-79f15830b6c9' User entered '98.1'	System	24 Sep 2020 00:17:33

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:17:09', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '607b3149-51c0-440d-a58a-79f15830b6c9'	System	24 Sep 2020 00:17:33
User entered 'No (N)'	System	24 Sep 2020 00:17:33

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:17:32', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '607b3149-51c0-440d-a58a-79f15830b6c9'	System	24 Sep 2020 00:17:33
User entered '23 Sep 2020 20:17'	System	24 Sep 2020 00:17:33

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:03:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '7e9269d6-ec60-42dc-abdc-8341327aa042'	System	17 Sep 2020 18:04:28
User entered 'None (1)'	System	17 Sep 2020 18:04:28

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:03:48', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '7e9269d6-ec60-42dc-abdc-8341327aa042'	System	17 Sep 2020 18:04:28
User entered 'No (N)'	System	17 Sep 2020 18:04:28

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '7e9269d6-ec60-42dc-abdc-8341327aa042'	System	17 Sep 2020 18:04:28
User entered 'No (N)'	System	17 Sep 2020 18:04:28

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:15', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '7e9269d6-ec60-42dc-abdc-8341327aa042'	System	17 Sep 2020 18:04:28
User entered 'None (1)'	System	17 Sep 2020 18:04:28

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '7e9269d6-ec60-42dc-abdc-8341327aa042'	System	17 Sep 2020 18:04:28
User entered '17 Sep 2020 14:04'	System	17 Sep 2020 18:04:28

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 13:44'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 16:14'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3cce4d1d-c8fe-478d-9e48-d1562c47cf63'	System	18 Sep 2020 00:35:14
User entered 'None (1)'	System	18 Sep 2020 00:35:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:46', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3cce4d1d-c8fe-478d-9e48-d1562c47cf63'	System	18 Sep 2020 00:35:14
User entered 'No (N)'	System	18 Sep 2020 00:35:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:34:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3cce4d1d-c8fe-478d-9e48-d1562c47cf63'	System	18 Sep 2020 00:35:14
User entered 'No (N)'	System	18 Sep 2020 00:35:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:01', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3cce4d1d-c8fe-478d-9e48-d1562c47cf63'	System	18 Sep 2020 00:35:14
User entered 'None (1)'	System	18 Sep 2020 00:35:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3cce4d1d-c8fe-478d-9e48-d1562c47cf63'	System	18 Sep 2020 00:35:14
User entered '17 Sep 2020 20:35'	System	18 Sep 2020 00:35:14

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 17:09'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 2'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:04:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4064b63f-4c47-4618-9800-63dde9c59e8d'	System	19 Sep 2020 00:07:37
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 00:07:37

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:04:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4064b63f-4c47-4618-9800-63dde9c59e8d'	System	19 Sep 2020 00:07:37
User entered 'No (N)'	System	19 Sep 2020 00:07:37

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:07:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4064b63f-4c47-4618-9800-63dde9c59e8d'	System	19 Sep 2020 00:07:37
User entered 'No (N)'	System	19 Sep 2020 00:07:37

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:06:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4064b63f-4c47-4618-9800-63dde9c59e8d'	System	19 Sep 2020 00:07:37
User entered 'None (1)'	System	19 Sep 2020 00:07:37

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:07:34', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4064b63f-4c47-4618-9800-63dde9c59e8d'	System	19 Sep 2020 00:07:37
User entered '18 Sep 2020 20:07'	System	19 Sep 2020 00:07:37

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 3'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:26:01', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '62ca43a4-c679-4941-8737-70bb87cdacb6'	System	20 Sep 2020 00:26:52
User entered 'None (1)'	System	20 Sep 2020 00:26:52

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:26:06', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '62ca43a4-c679-4941-8737-70bb87cdacb6'	System	20 Sep 2020 00:26:52
User entered 'No (N)'	System	20 Sep 2020 00:26:52

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:26:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '62ca43a4-c679-4941-8737-70bb87cdacb6'	System	20 Sep 2020 00:26:52
User entered 'No (N)'	System	20 Sep 2020 00:26:52

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:26:42', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '62ca43a4-c679-4941-8737-70bb87cdacb6'	System	20 Sep 2020 00:26:52
User entered 'None (1)'	System	20 Sep 2020 00:26:52

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:26:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '62ca43a4-c679-4941-8737-70bb87cdacb6'	System	20 Sep 2020 00:26:52
User entered '19 Sep 2020 20:26'	System	20 Sep 2020 00:26:52

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 4'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:22:57', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c921c04e-e0e4-4511-abd6-fcfde8bbaa3c'	System	21 Sep 2020 00:23:57
User entered 'None (1)'	System	21 Sep 2020 00:23:57

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:23:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c921c04e-e0e4-4511-abd6-fcfde8bbaa3c'	System	21 Sep 2020 00:23:57
User entered 'No (N)'	System	21 Sep 2020 00:23:57

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:23:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c921c04e-e0e4-4511-abd6-fcfde8bbaa3c'	System	21 Sep 2020 00:23:57
User entered 'No (N)'	System	21 Sep 2020 00:23:57

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:23:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c921c04e-e0e4-4511-abd6-fcfde8bbaa3c'	System	21 Sep 2020 00:23:57
User entered 'None (1)'	System	21 Sep 2020 00:23:57

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:23:55', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c921c04e-e0e4-4511-abd6-fcfde8bbaa3c'	System	21 Sep 2020 00:23:57
User entered '20 Sep 2020 20:23'	System	21 Sep 2020 00:23:57

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 5'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:15:58', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bae202ed-bc2e-43d1-8517-c1d8d607d3b0'	System	22 Sep 2020 00:16:13
User entered 'None (1)'	System	22 Sep 2020 00:16:13

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:02', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bae202ed-bc2e-43d1-8517-c1d8d607d3b0'	System	22 Sep 2020 00:16:13
User entered 'No (N)'	System	22 Sep 2020 00:16:13

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:04', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bae202ed-bc2e-43d1-8517-c1d8d607d3b0'	System	22 Sep 2020 00:16:13
User entered 'No (N)'	System	22 Sep 2020 00:16:13

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bae202ed-bc2e-43d1-8517-c1d8d607d3b0'	System	22 Sep 2020 00:16:13
User entered 'None (1)'	System	22 Sep 2020 00:16:13

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bae202ed-bc2e-43d1-8517-c1d8d607d3b0'	System	22 Sep 2020 00:16:13
User entered '21 Sep 2020 20:16'	System	22 Sep 2020 00:16:13

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 6'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3aadf15a-623a-43a6-9c59-bfeea82eeb31'	System	23 Sep 2020 00:16:38
User entered 'None (1)'	System	23 Sep 2020 00:16:38

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:20', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3aadf15a-623a-43a6-9c59-bfeea82eeb31'	System	23 Sep 2020 00:16:38
User entered 'No (N)'	System	23 Sep 2020 00:16:38

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:28', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3aadf15a-623a-43a6-9c59-bfeea82eeb31'	System	23 Sep 2020 00:16:38
User entered 'No (N)'	System	23 Sep 2020 00:16:38

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:33', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3aadf15a-623a-43a6-9c59-bfeea82eeb31'	System	23 Sep 2020 00:16:38
User entered 'None (1)'	System	23 Sep 2020 00:16:38

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:37', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3aadf15a-623a-43a6-9c59-bfeea82eeb31'	System	23 Sep 2020 00:16:38
User entered '22 Sep 2020 20:16'	System	23 Sep 2020 00:16:38

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 7'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:17:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '64a9b709-ccdb-4ddd-9ce2-e868a08d04fb'	System	24 Sep 2020 00:18:25
User entered 'None (1)'	System	24 Sep 2020 00:18:25

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:17:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '64a9b709-ccdb-4ddd-9ce2-e868a08d04fb'	System	24 Sep 2020 00:18:25
User entered 'No (N)'	System	24 Sep 2020 00:18:25

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '64a9b709-ccdb-4ddd-9ce2-e868a08d04fb'	System	24 Sep 2020 00:18:25
User entered 'No (N)'	System	24 Sep 2020 00:18:25

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:15', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '64a9b709-ccdb-4ddd-9ce2-e868a08d04fb'	System	24 Sep 2020 00:18:25
User entered 'None (1)'	System	24 Sep 2020 00:18:25

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:24', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '64a9b709-ccdb-4ddd-9ce2-e868a08d04fb'	System	24 Sep 2020 00:18:25
User entered '23 Sep 2020 20:18'	System	24 Sep 2020 00:18:25

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:46', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:52', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:04:59', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:05:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'None (0)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:05:08', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered 'No (N)'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T14:05:19', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '466d9dc4-d3ed-4703-b967-2e1982ad57a7'	System	17 Sep 2020 18:05:46
User entered '17 Sep 2020 14:05'	System	17 Sep 2020 18:05:46

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 13:44'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 16:14'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:35:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:36:02', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'None (0)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:36:09', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered 'No (N)'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-17T20:36:15', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'c2e07773-1b62-4373-aedb-9179111b4355'	System	18 Sep 2020 00:36:17
User entered '17 Sep 2020 20:36'	System	18 Sep 2020 00:36:17

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Sep 2020 17:09'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 2'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:07:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:21', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:34', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfb-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:44', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'None (0)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:08:53', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered 'No (N)'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-18T20:09:01', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dd2e0e0d-1bbc-4cfd-b577-2dcb68dd158c'	System	19 Sep 2020 00:09:04
User entered '18 Sep 2020 20:09'	System	19 Sep 2020 00:09:04

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 3'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:27:26', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:27:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:27:51', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:28:04', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:28:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:28:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'None (0)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:28:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered 'No (N)'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-19T20:28:21', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '488558b6-d0d0-4489-8a19-871ce9171dd9'	System	20 Sep 2020 00:28:23
User entered '19 Sep 2020 20:28'	System	20 Sep 2020 00:28:23

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 4'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:05', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:08', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:12', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:16', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:20', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:23', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'None (0)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered 'No (N)'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-20T20:24:44', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bed362f9-fb03-4c10-91f1-0ba3d3d37e10'	System	21 Sep 2020 00:24:49
User entered '20 Sep 2020 20:24'	System	21 Sep 2020 00:24:49

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 5'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:19', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:21', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:24', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:28', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:31', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:34', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'None (0)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered 'No (N)'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-21T20:16:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec8b178e-471b-4ffc-a674-6ad45601cc0a'	System	22 Sep 2020 00:16:43
User entered '21 Sep 2020 20:16'	System	22 Sep 2020 00:16:43

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 6'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:16:59', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:05', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:26', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:32', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'None (0)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered 'No (N)'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-22T20:17:58', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e1b8dd81-ab5a-47d6-b897-a2d4c5d67b97'	System	23 Sep 2020 00:17:59
User entered '22 Sep 2020 20:17'	System	23 Sep 2020 00:17:59

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 7'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:32', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:43', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'None (0)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:18:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered 'No (N)'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-09-23T20:19:02', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6ae9915e-eb8c-4453-b1c0-3a573c0d5e55'	System	24 Sep 2020 00:19:03
User entered '23 Sep 2020 20:19'	System	24 Sep 2020 00:19:03

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:30:30

US3622197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:14:26

US3622197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:14:26

US3622197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:14:26

US3622197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'unable to contact; multiple attempts made and messages left'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:14:26

US3622197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 14:14:32

US3622197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	09 Oct 2020 14:14:32

US3622197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Oct 2020 12:49:44

US3622197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered '1 Oct 2020'	Junlin Long (b) (4)	10 Oct 2020 12:49:44

US3622197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	10 Oct 2020 12:49:44

US3622197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'unable to contact; message left'	Junlin Long (b) (4)	10 Oct 2020 12:49:44

US3622197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Oct 2020 12:49:51

US3622197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	10 Oct 2020 12:49:51

US3622197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Yes (Y)'	Junlin Long (b) (4)	10 Oct 2020 12:50:25

US3622197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 05:27:32
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'message left on October 9th; patient finally returned the call on October 12th, stating no change to aes, medical history, etc.' (Site from System).	Junlin Long (b) (4) (b) (4)	12 Oct 2020 19:41:12
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Oct 2020 19:38:52
Signature has been broken.	Junlin Long (b) (4) (b) (4)	12 Oct 2020 19:38:52
User entered '12 Oct 2020' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	12 Oct 2020 19:38:52
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered '9 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	10 Oct 2020 12:50:25

US3622197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	12 Oct 2020 19:38:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Junlin Long (b) (4)	12 Oct 2020 19:38:52
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Junlin Long (b) (4)	10 Oct 2020 12:50:25
	(b) (4)	

US3622197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	12 Oct 2020 19:38:52
User entered empty; reason for change Data Entry Error	(b) (4)	
	Junlin Long (b) (4)	12 Oct 2020 19:38:52
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	10 Oct 2020 18:05:15
User entered 'unable to contact; message left'	(b) (4)	
	Junlin Long (b) (4)	10 Oct 2020 12:50:25
	(b) (4)	

US3622197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Oct 2020 19:41:24

US3622197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	12 Oct 2020 19:41:24

US3622197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 15:35:16

US3622197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 15:35:16

US3622197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	15 Oct 2020 15:35:16

US3622197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'VISIT2'	System	15 Oct 2020 15:35:16

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '10:53'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '15 Oct 2020 10:53'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '99.8' F	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '91'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'bpm'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '18'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'breaths/min'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '153'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '93'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '12:44'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '15 Oct 2020 12:44'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '98.4' F	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (Oral)'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '83'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'bpm'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '16'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'breaths/min'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '155'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '97'	Junlin Long (b) (4)	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	15 Oct 2020 17:47:56

US3622197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long	15 Oct 2020 17:48:03

US3622197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:48:03

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

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 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '12:13'	Junlin Long (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '15 Oct 2020 12:13'	System	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'ONCE'	System	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:15:34

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 16:21:45

US3622197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:48:23

US3622197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 17:48:23

US3622197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '11:05'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:48:23

US3622197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '15 Oct 2020 11:05'	System	15 Oct 2020 17:48:23

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '11:15'	Junlin Long (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '15 Oct 2020 11:15'	System	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered empty.	System	15 Oct 2020 17:48:33

US3622197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:48:36

US3622197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	15 Oct 2020 17:48:36

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 12:33'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:03'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:23:42', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0b036409-bde5-42bc-aa28-0ce9c0909cd5'	System	16 Oct 2020 01:24:40
User entered 'Yes (Y)'	System	16 Oct 2020 01:24:40

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:24:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0b036409-bde5-42bc-aa28-0ce9c0909cd5'	System	16 Oct 2020 01:24:40
User entered '97.6'	System	16 Oct 2020 01:24:40

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:24:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0b036409-bde5-42bc-aa28-0ce9c0909cd5'	System	16 Oct 2020 01:24:40
User entered 'No (N)'	System	16 Oct 2020 01:24:40

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:24:38', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0b036409-bde5-42bc-aa28-0ce9c0909cd5'	System	16 Oct 2020 01:24:40
User entered '15 Oct 2020 21:24'	System	16 Oct 2020 01:24:40

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:58'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 2'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:41', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'a1f628e5-a8a0-4a6c-a747-315b54dcda64'	System	17 Oct 2020 01:18:06
User entered 'Yes (Y)'	System	17 Oct 2020 01:18:06

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:17:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'a1f628e5-a8a0-4a6c-a747-315b54dcda64'	System	17 Oct 2020 01:18:06
User entered '97.7'	System	17 Oct 2020 01:18:06

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:17:53', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'a1f628e5-a8a0-4a6c-a747-315b54dcda64'	System	17 Oct 2020 01:18:06
User entered 'No (N)'	System	17 Oct 2020 01:18:06

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'a1f628e5-a8a0-4a6c-a747-315b54dcda64'	System	17 Oct 2020 01:18:06
User entered '16 Oct 2020 21:18'	System	17 Oct 2020 01:18:06

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 3'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:11:12', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e7d401c3-60cb-46e0-ba07-8f282a83fb01'	System	18 Oct 2020 01:12:38
User entered 'Yes (Y)'	System	18 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e7d401c3-60cb-46e0-ba07-8f282a83fb01'	System	18 Oct 2020 01:12:38
User entered '98.5'	System	18 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e7d401c3-60cb-46e0-ba07-8f282a83fb01'	System	18 Oct 2020 01:12:38
User entered 'No (N)'	System	18 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e7d401c3-60cb-46e0-ba07-8f282a83fb01'	System	18 Oct 2020 01:12:38
User entered '17 Oct 2020 21:12'	System	18 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 4'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:42:52', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec90135f-8f34-4eab-a9b5-e09539e36ef2'	System	19 Oct 2020 00:44:42
User entered 'Yes (Y)'	System	19 Oct 2020 00:44:42

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:15', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec90135f-8f34-4eab-a9b5-e09539e36ef2'	System	19 Oct 2020 00:44:42
User entered '98.1'	System	19 Oct 2020 00:44:42

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:37', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec90135f-8f34-4eab-a9b5-e09539e36ef2'	System	19 Oct 2020 00:44:42
User entered 'No (N)'	System	19 Oct 2020 00:44:42

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:41', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'ec90135f-8f34-4eab-a9b5-e09539e36ef2'	System	19 Oct 2020 00:44:42
User entered '18 Oct 2020 20:44'	System	19 Oct 2020 00:44:42

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 5'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:08:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe940bbf-c18f-4242-a947-db0dbed9a869'	System	20 Oct 2020 01:08:56
User entered 'Yes (Y)'	System	20 Oct 2020 01:08:56

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:08:42', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe940bbf-c18f-4242-a947-db0dbed9a869'	System	20 Oct 2020 01:08:56
User entered '98.4'	System	20 Oct 2020 01:08:56

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:08:48', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe940bbf-c18f-4242-a947-db0dbed9a869'	System	20 Oct 2020 01:08:56
User entered 'No (N)'	System	20 Oct 2020 01:08:56

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:08:55', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe940bbf-c18f-4242-a947-db0dbed9a869'	System	20 Oct 2020 01:08:56
User entered '19 Oct 2020 21:08'	System	20 Oct 2020 01:08:56

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 6'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '55d217ff-a270-4921-82fa-dbf97b1980ee'	System	21 Oct 2020 01:12:38
User entered 'Yes (Y)'	System	21 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:23', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '55d217ff-a270-4921-82fa-dbf97b1980ee' User entered '98.3'	System	21 Oct 2020 01:12:38
	System	21 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:27', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '55d217ff-a270-4921-82fa-dbf97b1980ee'	System	21 Oct 2020 01:12:38
User entered 'No (N)'	System	21 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:35', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '55d217ff-a270-4921-82fa-dbf97b1980ee'	System	21 Oct 2020 01:12:38
User entered '20 Oct 2020 21:12'	System	21 Oct 2020 01:12:38

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 7'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:56:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bda83766-6765-4396-ad9f-b0b71bc5cb7b'	System	22 Oct 2020 00:58:09
User entered 'Yes (Y)'	System	22 Oct 2020 00:58:09

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:57:32', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bda83766-6765-4396-ad9f-b0b71bc5cb7b' User entered '98.4'	System	22 Oct 2020 00:58:09
	System	22 Oct 2020 00:58:09

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:57:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bda83766-6765-4396-ad9f-b0b71bc5cb7b'	System	22 Oct 2020 00:58:09
User entered 'No (N)'	System	22 Oct 2020 00:58:09

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'bda83766-6765-4396-ad9f-b0b71bc5cb7b'	System	22 Oct 2020 00:58:09
User entered '21 Oct 2020 20:58'	System	22 Oct 2020 00:58:09

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 12:33'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:03'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:21:59', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd8950bb8-986f-4d4e-a98b-81540fc74a05'	System	16 Oct 2020 01:22:31
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 01:22:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:06', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd8950bb8-986f-4d4e-a98b-81540fc74a05'	System	16 Oct 2020 01:22:31
User entered 'No (N)'	System	16 Oct 2020 01:22:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd8950bb8-986f-4d4e-a98b-81540fc74a05'	System	16 Oct 2020 01:22:31
User entered 'No (N)'	System	16 Oct 2020 01:22:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd8950bb8-986f-4d4e-a98b-81540fc74a05'	System	16 Oct 2020 01:22:31
User entered 'None (1)'	System	16 Oct 2020 01:22:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:28', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd8950bb8-986f-4d4e-a98b-81540fc74a05'	System	16 Oct 2020 01:22:31
User entered '15 Oct 2020 21:22'	System	16 Oct 2020 01:22:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:58'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 2'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:02', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '711e352c-fc9d-480c-8138-9499d8d240e7'	System	17 Oct 2020 01:16:32
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 01:16:32

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '711e352c-fc9d-480c-8138-9499d8d240e7'	System	17 Oct 2020 01:16:32
User entered 'No (N)'	System	17 Oct 2020 01:16:32

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '711e352c-fc9d-480c-8138-9499d8d240e7'	System	17 Oct 2020 01:16:32
User entered 'No (N)'	System	17 Oct 2020 01:16:32

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:20', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '711e352c-fc9d-480c-8138-9499d8d240e7'	System	17 Oct 2020 01:16:32
User entered 'None (1)'	System	17 Oct 2020 01:16:32

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:16:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '711e352c-fc9d-480c-8138-9499d8d240e7'	System	17 Oct 2020 01:16:32
User entered '16 Oct 2020 21:16'	System	17 Oct 2020 01:16:32

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 3'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:42', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d55ece4-96d2-411f-987e-f78e39ddce38'	System	18 Oct 2020 01:13:13
User entered 'None (1)'	System	18 Oct 2020 01:13:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d55ece4-96d2-411f-987e-f78e39ddce38'	System	18 Oct 2020 01:13:13
User entered 'No (N)'	System	18 Oct 2020 01:13:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d55ece4-96d2-411f-987e-f78e39ddce38'	System	18 Oct 2020 01:13:13
User entered 'No (N)'	System	18 Oct 2020 01:13:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:12:57', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d55ece4-96d2-411f-987e-f78e39ddce38'	System	18 Oct 2020 01:13:13
User entered 'None (1)'	System	18 Oct 2020 01:13:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:10', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4d55ece4-96d2-411f-987e-f78e39ddce38'	System	18 Oct 2020 01:13:13
User entered '17 Oct 2020 21:13'	System	18 Oct 2020 01:13:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 4'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe1b4df1-1b16-429e-88c0-bf4a8b14f3a7'	System	19 Oct 2020 00:45:13
User entered 'None (1)'	System	19 Oct 2020 00:45:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:52', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe1b4df1-1b16-429e-88c0-bf4a8b14f3a7'	System	19 Oct 2020 00:45:13
User entered 'No (N)'	System	19 Oct 2020 00:45:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:44:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe1b4df1-1b16-429e-88c0-bf4a8b14f3a7'	System	19 Oct 2020 00:45:13
User entered 'No (N)'	System	19 Oct 2020 00:45:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe1b4df1-1b16-429e-88c0-bf4a8b14f3a7'	System	19 Oct 2020 00:45:13
User entered 'None (1)'	System	19 Oct 2020 00:45:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:12', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'fe1b4df1-1b16-429e-88c0-bf4a8b14f3a7'	System	19 Oct 2020 00:45:13
User entered '18 Oct 2020 20:45'	System	19 Oct 2020 00:45:13

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 5'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:09', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '89b0d58f-c0a7-4b6c-8130-c80dbcc34dfd'	System	20 Oct 2020 01:09:31
User entered 'None (1)'	System	20 Oct 2020 01:09:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '89b0d58f-c0a7-4b6c-8130-c80dbcc34dfd'	System	20 Oct 2020 01:09:31
User entered 'No (N)'	System	20 Oct 2020 01:09:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '89b0d58f-c0a7-4b6c-8130-c80dbcc34dfd'	System	20 Oct 2020 01:09:31
User entered 'No (N)'	System	20 Oct 2020 01:09:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:23', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '89b0d58f-c0a7-4b6c-8130-c80dbcc34dfd'	System	20 Oct 2020 01:09:31
User entered 'None (1)'	System	20 Oct 2020 01:09:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:28', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '89b0d58f-c0a7-4b6c-8130-c80dbcc34dfd'	System	20 Oct 2020 01:09:31
User entered '19 Oct 2020 21:09'	System	20 Oct 2020 01:09:31

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 6'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b48cf59-5948-4059-9bb2-6d6e7c1e9a42'	System	21 Oct 2020 01:13:09
User entered 'None (1)'	System	21 Oct 2020 01:13:09

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b48cf59-5948-4059-9bb2-6d6e7c1e9a42'	System	21 Oct 2020 01:13:09
User entered 'No (N)'	System	21 Oct 2020 01:13:09

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:53', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b48cf59-5948-4059-9bb2-6d6e7c1e9a42'	System	21 Oct 2020 01:13:09
User entered 'No (N)'	System	21 Oct 2020 01:13:09

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:12:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b48cf59-5948-4059-9bb2-6d6e7c1e9a42'	System	21 Oct 2020 01:13:09
User entered 'None (1)'	System	21 Oct 2020 01:13:09

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b48cf59-5948-4059-9bb2-6d6e7c1e9a42'	System	21 Oct 2020 01:13:09
User entered '20 Oct 2020 21:13'	System	21 Oct 2020 01:13:09

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 7'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:12', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f717ee0d-49ab-46c6-9193-b48f07aeb378'	System	22 Oct 2020 00:58:39
User entered 'None (1)'	System	22 Oct 2020 00:58:39

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:16', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f717ee0d-49ab-46c6-9193-b48f07aeb378'	System	22 Oct 2020 00:58:39
User entered 'No (N)'	System	22 Oct 2020 00:58:39

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:24', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f717ee0d-49ab-46c6-9193-b48f07aeb378'	System	22 Oct 2020 00:58:39
User entered 'No (N)'	System	22 Oct 2020 00:58:39

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f717ee0d-49ab-46c6-9193-b48f07aeb378'	System	22 Oct 2020 00:58:39
User entered 'None (1)'	System	22 Oct 2020 00:58:39

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:35', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f717ee0d-49ab-46c6-9193-b48f07aeb378'	System	22 Oct 2020 00:58:39
User entered '21 Oct 2020 20:58'	System	22 Oct 2020 00:58:39

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 12:33'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:03'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:38', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:42', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:46', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:22:57', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'None (0)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:23:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered 'No (N)'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-15T21:23:06', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '5b9db8e3-2dca-4092-a0d6-9bed03d33fca'	System	16 Oct 2020 01:23:09
User entered '15 Oct 2020 21:23'	System	16 Oct 2020 01:23:09

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '15 Oct 2020 15:58'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 2'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:06', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:09', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:15', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:21', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'None (0)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered 'No (N)'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-16T21:18:38', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '78d37c64-2ef9-4025-8ea1-0847af8cf647'	System	17 Oct 2020 01:18:41
User entered '16 Oct 2020 21:18'	System	17 Oct 2020 01:18:41

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 3'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:24', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:27', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:31', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:34', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:37', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'None (0)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:39', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered 'No (N)'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-17T21:13:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '49ba7c70-0063-4425-aae2-e2308a6acfc9'	System	18 Oct 2020 01:13:48
User entered '17 Oct 2020 21:13'	System	18 Oct 2020 01:13:48

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 4'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:27', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:33', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:37', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:41', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'None (0)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:45:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered 'No (N)'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-18T20:46:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '25d52c07-5874-450e-923c-97165beced7a'	System	19 Oct 2020 00:46:05
User entered '18 Oct 2020 20:46'	System	19 Oct 2020 00:46:05

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 5'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:43', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:46', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:49', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:52', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'None (0)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:09:55', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered 'No (N)'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-19T21:10:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'd7acfdfa-27b2-4fba-a09b-c5000b2d266a'	System	20 Oct 2020 01:10:03
User entered '19 Oct 2020 21:10'	System	20 Oct 2020 01:10:03

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 6'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:20', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:28', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:33', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'None (0)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:40', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered 'No (N)'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-20T21:13:44', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '02c9e62b-d07e-4fe4-8820-c7e0c69e35c1'	System	21 Oct 2020 01:13:46
User entered '20 Oct 2020 21:13'	System	21 Oct 2020 01:13:46

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
Data entry locked.	System	15 Oct 2020 16:21:45
User entered 'Day 7'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:50', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:53', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:58:57', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:59:04', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:59:08', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'None (0)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:59:12', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered 'No (N)'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-10-21T20:59:17', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6fbfcb1d-d691-4e8c-aa8e-93976257e659'	System	22 Oct 2020 00:59:19
User entered '21 Oct 2020 20:59'	System	22 Oct 2020 00:59:19

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:21:45

US3622197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:23:18
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:21:45

US3622197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Oct 2020 18:38:59

US3622197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User entered '22 Oct 2020'	Junlin Long (b) (4)	22 Oct 2020 18:38:59

US3622197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	22 Oct 2020 18:38:59

US3622197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User entered empty.	Junlin Long (b) (4)	22 Oct 2020 18:38:59

US3622197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:03:38
User entered 'Yes (Y)'	Junlin Long (b) (4)	22 Oct 2020 18:39:02

US3622197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	22 Oct 2020 18:39:02

US3622197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Oct 2020 18:51:57

US3622197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:20
User entered '29 Oct 2020'	Junlin Long (b) (4)	29 Oct 2020 18:51:57

US3622197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:20
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	29 Oct 2020 18:51:57

US3622197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:20
User entered empty.	Junlin Long (b) (4)	29 Oct 2020 18:51:57

US3622197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:20
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Oct 2020 18:52:03

US3622197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	29 Oct 2020 18:52:03

US3622197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:30
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Nov 2020 16:21:46

US3622197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:30
User entered '5 Nov 2020'	Junlin Long (b) (4)	05 Nov 2020 16:21:46

US3622197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:30
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	05 Nov 2020 16:21:46

US3622197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:30
User entered empty.	Junlin Long (b) (4)	05 Nov 2020 16:21:46

US3622197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:36:30
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Nov 2020 16:21:49

US3622197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	05 Nov 2020 16:21:49

US3622197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Yes (Y)'	Junlin Long	12 Nov 2020 16:19:57

US3622197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '12 Nov 2020'	Junlin Long	12 Nov 2020 16:19:57

US3622197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	12 Nov 2020 16:19:57

US3622197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'VISIT3'	System	12 Nov 2020 16:19:57

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '12 Nov 2020'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '10:45'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '12 Nov 2020 10:45'	System	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '99.5' F	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Oral (Oral)'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '91'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'bpm'	System	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '20'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'breaths/min'	System	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '139'	Junlin Long	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '92'	Junlin Long (b) (4)	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered 'mmHg'	System	12 Nov 2020 16:20:19

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27

US3622197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27

US3622197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'No (N)'	Junlin Long (b) (4)	12 Nov 2020 16:20:23

US3622197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered empty.	Junlin Long (b) (4)	12 Nov 2020 16:20:23

US3622197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Nov 2020 16:20:34

US3622197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '12 Nov 2020'	Junlin Long (b) (4)	12 Nov 2020 16:20:34

US3622197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered '11:00'	(b) (4) Junlin Long (b) (4) (b) (4)	12 Nov 2020 16:20:34

US3622197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '12 Nov 2020 11:00'	System	12 Nov 2020 16:20:34

US3622197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:06:18
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Nov 2020 16:20:37

US3622197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	12 Nov 2020 16:20:37

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46
Data entry locked.	System	17 Sep 2020 17:30:30
User entered 'Day 64'	System	17 Sep 2020 17:30:30

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Have you been exposed to someone with 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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Please 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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Please 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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Please 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 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46
Data entry locked.	System	17 Sep 2020 17:30:30
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 17:30:30

US3622197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:16:46
Data entry locked.	System	17 Sep 2020 17:30:30
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 17:30:30

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2020-11-21T14:34:29', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '583f9a0f-74d1-4b69-9cc7-22e9cf0dcc2c'	System	21 Nov 2020 19:34:47
User entered 'No (N)'	System	21 Nov 2020 19:34:47

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2020-11-21T14:34:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '583f9a0f-74d1-4b69-9cc7-22e9cf0dcc2c'	System	21 Nov 2020 19:34:47
User entered 'No (N)'	System	21 Nov 2020 19:34:47

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-11-21T14:34:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '583f9a0f-74d1-4b69-9cc7-22e9cf0dcc2c'	System	21 Nov 2020 19:34:47
User entered '21 Nov 2020 14:34:45'	System	21 Nov 2020 19:34:47

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2020-11-30T12:55:25', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e58f1c69-4167-41d9-b898-7ee040bf7ed9'	System	30 Nov 2020 17:55:51
User entered 'No (N)'	System	30 Nov 2020 17:55:51

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2020-11-30T12:55:38', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e58f1c69-4167-41d9-b898-7ee040bf7ed9'	System	30 Nov 2020 17:55:51
User entered 'No (N)'	System	30 Nov 2020 17:55:51

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2020-11-30T12:55:48', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e58f1c69-4167-41d9-b898-7ee040bf7ed9' User entered '30 Nov 2020 12:55:48'	System	30 Nov 2020 17:55:51
	System	30 Nov 2020 17:55:51

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 (3a29c9cf93b18635)', Time: '2021-01-13T22:28:16', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e'	System	14 Jan 2021 03:29:37
User entered 'Yes (Y)'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-01-13T22:28:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e'	System	14 Jan 2021 03:29:37
User entered 'No (N)'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-01-13T22:28:35', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e'	System	14 Jan 2021 03:29:37
User entered 'No (N)'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-01-13T22:29:03', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e'	System	14 Jan 2021 03:29:37
User entered 'Yes (Y)'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Please 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 (3a29c9cf93b18635)', Time: '2021-01-13T22:29:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e'	System	14 Jan 2021 03:29:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-01-13T22:29:26', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f534a684-f570-44d6-abf5-1c39ead7b04e' User entered '13 Jan 2021 22:29:26'	System	14 Jan 2021 03:29:37

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-01-20T10:26:56', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8219b0e7-f0fe-4197-ada5-89d89bee596e'	System	20 Jan 2021 15:27:10
User entered 'No (N)'	System	20 Jan 2021 15:27:10

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-01-20T10:27:01', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8219b0e7-f0fe-4197-ada5-89d89bee596e'	System	20 Jan 2021 15:27:10
User entered 'No (N)'	System	20 Jan 2021 15:27:10

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-01-20T10:27:07', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8219b0e7-f0fe-4197-ada5-89d89bee596e' User entered '20 Jan 2021 10:27:07'	System	20 Jan 2021 15:27:10

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-01-24T14:09:10', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e780261b-429a-49fb-ab8d-5a1c5c212eab'	System	24 Jan 2021 19:09:20
User entered 'No (N)'	System	24 Jan 2021 19:09:20

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-01-24T14:09:14', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e780261b-429a-49fb-ab8d-5a1c5c212eab'	System	24 Jan 2021 19:09:20
User entered 'No (N)'	System	24 Jan 2021 19:09:20

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-01-24T14:09:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'e780261b-429a-49fb-ab8d-5a1c5c212eab' User entered '24 Jan 2021 14:09:18'	System	24 Jan 2021 19:09:20

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-02-02T08:54:11', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'cf086dfe-c027-4479-8bc3-043a6144b740'	System	02 Feb 2021 13:54:22
User entered 'No (N)'	System	02 Feb 2021 13:54:22

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-02-02T08:54:14', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'cf086dfe-c027-4479-8bc3-043a6144b740'	System	02 Feb 2021 13:54:22
User entered 'No (N)'	System	02 Feb 2021 13:54:22

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-02-02T08:54:18', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'cf086dfe-c027-4479-8bc3-043a6144b740'	System	02 Feb 2021 13:54:22
User entered '02 Feb 2021 08:54:18'	System	02 Feb 2021 13:54:22

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-02-10T15:18:13', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '392c05b0-7cbb-4718-bb65-18a3a197d9b7'	System	10 Feb 2021 20:18:25
User entered 'No (N)'	System	10 Feb 2021 20:18:25

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-02-10T15:18:16', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '392c05b0-7cbb-4718-bb65-18a3a197d9b7'	System	10 Feb 2021 20:18:25
User entered 'No (N)'	System	10 Feb 2021 20:18:25

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-02-10T15:18:20', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '392c05b0-7cbb-4718-bb65-18a3a197d9b7'	System	10 Feb 2021 20:18:25
User entered '10 Feb 2021 15:18:20'	System	10 Feb 2021 20:18:25

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 (3a29c9cf93b18635)', Time: '2021-02-15T17:26:45', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3ee86757-197a-4783-b24c-6893e5c15c92'	System	15 Feb 2021 22:26:55
User entered 'No (N)'	System	15 Feb 2021 22:26:55

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-02-15T17:26:47', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3ee86757-197a-4783-b24c-6893e5c15c92'	System	15 Feb 2021 22:26:55
User entered 'No (N)'	System	15 Feb 2021 22:26:55

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-02-15T17:26:51', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '3ee86757-197a-4783-b24c-6893e5c15c92'	System	15 Feb 2021 22:26:55
User entered '15 Feb 2021 17:26:51'	System	15 Feb 2021 22:26:55

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-02-23T12:04:24', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0d27c8a8-e95a-45df-837c-74dd63fb5039'	System	23 Feb 2021 17:16:58
User entered 'No (N)'	System	23 Feb 2021 17:16:58

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-02-23T12:04:31', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0d27c8a8-e95a-45df-837c-74dd63fb5039'	System	23 Feb 2021 17:16:58
User entered 'No (N)'	System	23 Feb 2021 17:16:58

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-02-23T12:04:36', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '0d27c8a8-e95a-45df-837c-74dd63fb5039'	System	23 Feb 2021 17:16:58
User entered '23 Feb 2021 12:04:36'	System	23 Feb 2021 17:16:58

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-03-01T17:52:21', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1b41e615-31e9-4440-854e-ec6fe5bd26ea'	System	01 Mar 2021 22:52:36
User entered 'No (N)'	System	01 Mar 2021 22:52:36

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-03-01T17:52:26', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1b41e615-31e9-4440-854e-ec6fe5bd26ea'	System	01 Mar 2021 22:52:36
User entered 'No (N)'	System	01 Mar 2021 22:52:36

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-01T17:52:30', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1b41e615-31e9-4440-854e-ec6fe5bd26ea'	System	01 Mar 2021 22:52:36
User entered '01 Mar 2021 17:52:30'	System	01 Mar 2021 22:52:36

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

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 (3a29c9cf93b18635)', Time: '2021-03-08T12:30:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4c923aa5-fd0c-40c8-9a8d-93d2b0c6a92c'	System	08 Mar 2021 17:32:35
User entered 'No (N)'	System	08 Mar 2021 17:32:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-03-08T12:30:58', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4c923aa5-fd0c-40c8-9a8d-93d2b0c6a92c'	System	08 Mar 2021 17:32:35
User entered 'No (N)'	System	08 Mar 2021 17:32:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-08T12:31:02', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '4c923aa5-fd0c-40c8-9a8d-93d2b0c6a92c'	System	08 Mar 2021 17:32:35
User entered '08 Mar 2021 12:31:02'	System	08 Mar 2021 17:32:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-03-15T09:35:07-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1fcafb9-b0e3-48f8-8746-f0b7930571cf' User entered 'No (N)'	System	15 Mar 2021 13:35:32

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-03-15T09:35:22-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1fcafb9-b0e3-48f8-8746-f0b7930571cf'	System	15 Mar 2021 13:35:32
User entered 'No (N)'	System	15 Mar 2021 13:35:32

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-15T09:35:27-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1fcafb9-b0e3-48f8-8746-f0b7930571cf' User entered '15 Mar 2021 09:35:27'	System	15 Mar 2021 13:35:32
	System	15 Mar 2021 13:35:32

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-03-22T17:03:21-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1a260838-6d76-46ad-b58f-ee218667061d' User entered 'No (N)'	System	22 Mar 2021 21:03:33
	System	22 Mar 2021 21:03:33

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-03-22T17:03:27-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1a260838-6d76-46ad-b58f-ee218667061d'	System	22 Mar 2021 21:03:33
User entered 'No (N)'	System	22 Mar 2021 21:03:33

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-22T17:03:29-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '1a260838-6d76-46ad-b58f-ee218667061d'	System	22 Mar 2021 21:03:33
User entered '22 Mar 2021 17:03:29'	System	22 Mar 2021 21:03:33

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-03-30T13:32:19-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '14031c7a-133c-4595-8c89-ab54e4b8b4b7'	System	30 Mar 2021 17:32:34
User entered 'No (N)'	System	30 Mar 2021 17:32:34

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-03-30T13:32:26-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '14031c7a-133c-4595-8c89-ab54e4b8b4b7'	System	30 Mar 2021 17:32:34
User entered 'No (N)'	System	30 Mar 2021 17:32:34

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-30T13:32:29-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '14031c7a-133c-4595-8c89-ab54e4b8b4b7'	System	30 Mar 2021 17:32:34
User entered '30 Mar 2021 13:32:29'	System	30 Mar 2021 17:32:34

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-04-05T19:36:21-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8b9e1b54-3211-4c64-bf1c-d8e1904dcacd'	System	05 Apr 2021 23:36:29
User entered 'No (N)'	System	05 Apr 2021 23:36:29

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-04-05T19:36:25-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8b9e1b54-3211-4c64-bf1c-d8e1904dcacd'	System	05 Apr 2021 23:36:29
User entered 'No (N)'	System	05 Apr 2021 23:36:29

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-04-05T19:36:28-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '8b9e1b54-3211-4c64-bf1c-d8e1904dcacd'	System	05 Apr 2021 23:36:29
User entered '05 Apr 2021 19:36:28'	System	05 Apr 2021 23:36:29

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-04-10T12:21:12-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6b43f03b-9221-4bc0-98a7-d23153dc3c09'	System	10 Apr 2021 16:21:35
User entered 'No (N)'	System	10 Apr 2021 16:21:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-04-10T12:21:19-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6b43f03b-9221-4bc0-98a7-d23153dc3c09'	System	10 Apr 2021 16:21:35
User entered 'No (N)'	System	10 Apr 2021 16:21:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-04-10T12:21:27-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: '6b43f03b-9221-4bc0-98a7-d23153dc3c09'	System	10 Apr 2021 16:21:35
User entered '10 Apr 2021 12:21:27'	System	10 Apr 2021 16:21:35

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-04-18T09:52:02-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'b7016689-8195-4de1-8bb9-28e3dad6498c'	System	18 Apr 2021 13:52:43
User entered 'No (N)'	System	18 Apr 2021 13:52:43

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-04-18T09:52:10-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'b7016689-8195-4de1-8bb9-28e3dad6498c'	System	18 Apr 2021 13:52:43
User entered 'No (N)'	System	18 Apr 2021 13:52:43

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-04-18T09:52:14-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'b7016689-8195-4de1-8bb9-28e3dad6498c'	System	18 Apr 2021 13:52:43
User entered '18 Apr 2021 09:52:14'	System	18 Apr 2021 13:52:43

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[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 (3a29c9cf93b18635)', Time: '2021-04-26T23:06:06-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dbec210a-5f69-4950-842a-a93383cf6f0b'	System	27 Apr 2021 03:06:16
User entered 'No (N)'	System	27 Apr 2021 03:06:16

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

Have you been exposed to someone with 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 (3a29c9cf93b18635)', Time: '2021-04-26T23:06:09-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dbec210a-5f69-4950-842a-a93383cf6f0b'	System	27 Apr 2021 03:06:16
User entered 'No (N)'	System	27 Apr 2021 03:06:16

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-04-26T23:06:13-04:00', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'dbec210a-5f69-4950-842a-a93383cf6f0b'	System	27 Apr 2021 03:06:16
User entered '26 Apr 2021 23:06:13'	System	27 Apr 2021 03:06:16

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:16:46

US3622197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:15:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:16:46
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:16:46

US3622197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:15:34

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 11:52:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-01T17:52:51', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f5fb0054-f804-4035-89bc-9a6b249326cb'	System	01 Mar 2021 22:52:57
User entered 'No (N)'	System	01 Mar 2021 22:52:57

US3622197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:15:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:52:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3a29c9cf93b18635)', Time: '2021-03-01T17:52:54', User OID: 'PatientReportedOutcome (US3622197)', ODM File OID: 'f5fb0054-f804-4035-89bc-9a6b249326cb'	System	01 Mar 2021 22:52:57
User entered '01 Mar 2021 17:52:54'	System	01 Mar 2021 22:52:57

US3622197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Dec 2020 14:22:17

US3622197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered '11 Dec 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	11 Dec 2020 14:22:17

US3622197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	11 Dec 2020 14:22:17

US3622197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'unable to contact; messages left'	Junlin Long (b) (4)	11 Dec 2020 14:22:17

US3622197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Jan 2021 17:15:33

US3622197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:03:27
User entered '1'	System	13 Jan 2021 17:15:33

US3622197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 17:15:50

US3622197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered '13 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 17:15:50

US3622197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 17:15:50

US3622197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 17:15:50

US3622197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 17:15:55

US3622197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User entered '1'	System	13 Jan 2021 17:15:55

US3622197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:05:45

US3622197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:05:45

US3622197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:05:45

US3622197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:05:45

US3622197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:05:51

US3622197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User entered '1'	System	11 Feb 2021 16:05:51

US3622197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:16:56

US3622197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:16:56

US3622197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:16:56

US3622197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:15:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:16:56

US3622197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:17:03

US3622197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:36:36
User entered '1'	System	16 Mar 2021 15:17:03

US3622197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 15:50:20

US3622197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '8 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 15:50:20

US3622197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[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 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Apr 2021 15:50:20

US3622197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered 'VISIT4'	System	08 Apr 2021 15:50:20

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '8 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '10:40'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered '8 Apr 2021 10:40'	System	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '98.7' F	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered 'bpm'	System	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered 'breaths/min'	System	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '141'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered 'mmHg'	System	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '74'	(b) (4), (b) (6)	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered 'mmHg'	System	08 Apr 2021 15:50:54

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50

US3622197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:15:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50

US3622197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 15:51:05

US3622197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 15:51:05

US3622197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 15:51:33

US3622197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '8 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 15:51:33

US3622197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered '11:10'	(b) (4), (b) (6)	08 Apr 2021 15:51:33

US3622197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered '8 Apr 2021 11:10'	System	08 Apr 2021 15:51:33

US3622197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 15:51:41

US3622197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:15:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:55:50
User entered '1'	System	08 Apr 2021 15:51:41

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:03:55

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:03:55

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[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 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	28 Jan 2021 16:03:55

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:15:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 16:03:55

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[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 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:03
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:37:20

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:15:03
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 19:37:20

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'mRNA-1273 (mRNA-1273)'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)'	Junlin Long (b) (4)	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:15:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered empty.	System	28 Jan 2021 16:04:06

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Jan 2021 16:04:26

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:04:26

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '10:05'	Junlin Long (b) (4)	28 Jan 2021 16:04:26

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:15:34

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '28 Jan 2021 10:05'	System	28 Jan 2021 16:04:26

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long	28 Jan 2021 16:04:34

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:34

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '28 Jan 2021'	Junlin Long (b) (4)	28 Jan 2021 16:04:34

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:34

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '10:00'	Junlin Long (b) (4)	28 Jan 2021 16:04:34

US3622197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:15:34

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:04:41
User entered '28 Jan 2021 10:00'	System	28 Jan 2021 16:04:34

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:34

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:40
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '25 Feb 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:22:35

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:34

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:40
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:22:35

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:34

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:40
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:22:35

US3622197

Folder: **Unscheduled 25 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **10 Jun 2021 09:15:34**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:40
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:22:35

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 10 Jun 2021 09:15:34

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:40
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	25 Feb 2021 19:22:35

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	25 Feb 2021 19:22:43

US3622197

Folder: Unscheduled 25 Feb 2021

Form: Physical Examination

Generated On: 10 Jun 2021 09:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:53:44
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '25 Feb 2021'	Junlin Long (b) (4)	25 Feb 2021 19:22:43

US3622197

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:15:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:19
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:47
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	13 Jan 2021 14:43:31
User entered 'No (N)'	Junlin Long (b) (4)	14 Dec 2020 14:25:29

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:10
User entered 'USA-US085-2021-mRNA-1273-P301000002'	System	13 Jan 2021 23:38:06
User entered 'New'	(b) (4), (b) (6)	13 Jan 2021 23:38:06

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia aggravated - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	29 Jan 2021 14:35:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	29 Jan 2021 14:35:19
Data point term sent to Coder	System	29 Jan 2021 14:34:50
Coding entries removed.	Junlin Long (b) (4)	29 Jan 2021 14:34:18
User entered 'worsening ANEMIA' reason for change: New Information	(b) (4) Junlin Long (b) (4)	29 Jan 2021 14:34:18
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	13 Jan 2021 14:51:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Jan 2021 14:51:01
Data point term sent to Coder	System	13 Jan 2021 14:50:07
User entered 'anemia'	Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
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 DM).	(b) (4), (b) (6)	27 Apr 2021 10:50:48
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 'Event end date already provided. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:22:01
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:57:52
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	29 Jan 2021 14:34:18
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4)	13 Jan 2021 14:49:46
	(b) (4)	

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '15 Jan 2021' reason for change: New Information	Junlin Long (b) (4)	29 Jan 2021 14:34:18
User entered empty.	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:39:33
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)	25 Jan 2021 19:09:28
User entered empty.	System	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Grade 4 (Grade 4)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:09:00
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records have been sent to the email on January 29th, 2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:25:41
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		28 Jan 2021 16:57:01
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		28 Jan 2021 16:57:01
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:09:58
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Jan 2021 14:49:46
User entered '1'	Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '12 Jan 2021'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:09:28
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	28 Jan 2021 16:57:16
User entered '15 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	28 Jan 2021 16:56:48
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:09:18
User entered empty.	Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'No (N)' reason for change: New Information	(b) (4) Junlin Long (b) (4)	28 Jan 2021 16:57:01
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '0'	Junlin Long	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Not Related (NOT RELATED)'	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	29 Jan 2021 14:34:18
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Jan 2021 14:49:46
User entered '0'	Junlin Long (b) (4)	13 Jan 2021 14:49:46
	(b) (4)	

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '1' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:34:18
User entered '0'	(b) (4)	
	Junlin Long (b) (4)	13 Jan 2021 14:49:46
	(b) (4)	

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '1' reason for change: New Information	(b) (4)	29 Jan 2021 14:34:18
User entered '0'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:09:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'provided' (Site from Safety).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:34:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:34:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:09:37
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ADDITIONAL HISTORY: DEPRESSION, MIGRAINE, SCIATICA, BILATERAL FOOT TENDONITIS, CHRONIC BRONCHITIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 08:51:49
User closed query 'Per DM CLR: Narrative = HISTORY OF MICROCYTIC IRON DEFICIENCY ANEMIA WITH A GI BLEED IN JUNE 2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:08:15
User closed query 'Per DM CLR: Narrative = LABS ON 01/12/2021 REVEALED A HEMOGLOBIN OF 5.2, RBC 2.7, HEMATOCRIT 20.8, MCV 76.8, MCH 19.2 MCHC 25, RDW-CV 18.5, IRON 17, TIBC 495, AND IRON SATURATION 3. FOBT WAS NEGATIVE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:04:18
User closed query 'Per DM CLR: Narrative = IV FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:01:16
Query 'Per DM CLR: Narrative = IV FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'conmed updated' (Site from DM).	Junlin Long (b) (4)	03 Mar 2021 14:05:34

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = LABS ON 01/12/2021 REVEALED A HEMOGLOBIN OF 5.2, RBC 2.7, HEMATOCRIT 20.8, MCV 76.8, MCH 19.2 MCHC 25, RDW-CV 18.5, IRON 17, TIBC 495, AND IRON SATURATION 3. FOBT WAS NEGATIVE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'conproc updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:05:27
Query 'Per DM CLR: Narrative = ADDITIONAL HISTORY: DEPRESSION, MIGRAINE, SCIATICA, BILATERAL FOOT TENDONITIS, CHRONIC BRONCHITIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'mh updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:05:01
Query 'Per DM CLR: Narrative = HISTORY OF MICROCYTIC IRON DEFICIENCY ANEMIA WITH A GI BLEED IN JUNE 2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'mh updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	03 Mar 2021 14:04:37
User opened query 'Per DM CLR: Narrative = ADDITIONAL HISTORY: DEPRESSION, MIGRAINE, SCIATICA, BILATERAL FOOT TENDONITIS, CHRONIC BRONCHITIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:42:39
User opened query 'Per DM CLR: Narrative = HISTORY OF MICROCYTIC IRON DEFICIENCY ANEMIA WITH A GI BLEED IN JUNE 2020. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:42:31

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = IV FLUIDS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:42:25
User opened query 'Per DM CLR: Narrative = LABS ON 01/12/2021 REVEALED A HEMOGLOBIN OF 5.2, RBC 2.7, HEMATOCRIT 20.8, MCV 76.8, MCH 19.2 MCHC 25, RDW-CV 18.5, IRON 17, TIBC 495, AND IRON SATURATION 3. FOBT WAS NEGATIVE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:42:20
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:23:41
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 21:09:21
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)	29 Jan 2021 21:09:18
User closed query 'PV Query: Was the subject tested for COVID-19 upon admission to the hospital? If yes, please provide date of test, type of test and results.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:09:07
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 'updated' (Site from Safety).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:37:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Junlin Long (b) (4)	29 Jan 2021 14:36:49
User entered 'PARTICIPANT REPORTED DURING MONTH 4 SAFETY CALL THAT THEY WERE HOSPITALIZED DUE TO ANEMIA.	Junlin Long (b) (4)	29 Jan 2021 14:36:40

update: The participant was admitted in the hospital from 01/12/2021 through 01/15/2021. She went to the ER with complaints of shortness of breath, fatigue, and weakness. Labs on 01/12/2021 revealed a hemoglobin of 5.2, RBC 2.7, hematocrit 20.8, MCV 76.8, MCH 19.2 MCHC 25, RDW-CV 18.5, iron 17, TIBC 495, and iron saturation 3. FOBT was negative and COVID test on 01/12/2021 was negative. Chest X-ray on 01/12/2021 was without acute pathology and EKG with NSR. The participant received 2 units of PRBC's on 01/13/2021 and 1 unit of PRBC's on 01/15/2021. She was discharged on 01/15/2021 in stable condition with a hemoglobin of 8.6. While admitted she received Venofir 200mg IV daily, B12 1,000mcg IM daily, Ativan 1mg for insomnia once on 01/13/2021, Protonix 40 mg PO daily, Norvasc 5mg PO daily, and IV fluids. She has a known history of microcytic iron deficiency anemia with a GI bleed in June 2020 per medical records. Additional history per medical records includes COPD, depression, HTN, migraine, sciatica, bilateral foot tendonitis, chronic bronchitis, and insomnia.' reason for change: Per Query Resolution

Query 'PV Query: Was the subject tested for COVID-19 upon admission to the hospital? If yes, please provide date of test, type of test and results.' answered with 'participant was tested covid-19 negative on January 12th, 2021.' (Site from Safety).	Junlin Long (b) (4)	29 Jan 2021 14:35:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[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)	25 Jan 2021 19:09:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:09:44
User opened query 'PV Query: Was the subject tested for COVID-19 upon admission to the hospital? If yes, please provide date of test, type of test and results.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:09:10
User entered 'participant reported during month 4 safety call that they were hospitalized due to anemia.'	Junlin Long (b) (4)	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 14:49:46

US3622197

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:15:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 16:57:01

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
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: Musculoskeletal chest pain, LLT: Rib pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Mar 2021 19:32:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Mar 2021 19:32:27
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Mar 2021 16:12:44
Data point term sent to Coder	System	19 Mar 2021 14:15:59
User entered 'bilateral ribcage pain'	Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Yes (Y)'	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '22 Feb 2021'	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User entered empty.	System	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'No (N)'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '6 Mar 2021'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User entered empty.	System	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'No (N)'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Not Related (NOT RELATED)'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '1'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered '0'	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 16:12:44
User entered empty.	Junlin Long	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User entered '0'	System	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19
User entered '1'	System	19 Mar 2021 14:15:54

US3622197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:15:34

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:19

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:15:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:37
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:49:28

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:52:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:52:27
Data point term sent to Coder	System	15 Oct 2020 17:51:13
User entered 'ferrous sulfate'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 06:17:11
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:07:02
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:06:57
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:06:57
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:46:32
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'anemia'	Junlin Long (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
User closed query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 09:11:49
Query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	17 Mar 2021 17:17:57
Signature has been broken.	Junlin Long (b) (4) (b) (4)	17 Mar 2021 17:17:51
User entered '325' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	17 Mar 2021 17:17:51
User opened query 'Per DM CLR: Please provide the specific dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:13:06
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 20:08:13
User entered '1'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:04:48
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	17 Mar 2021 17:17:51
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	17 Mar 2021 17:17:51
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'tablet (TABLET)'	(b) (4)	
	Junlin Long (b) (4)	15 Oct 2020 17:51:08
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (ORAL)'	Junlin Long	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '0'	Junlin Long (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long (b) (4)	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:51:08

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:53:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:53:34
Data point term sent to Coder User entered 'amlodipine'	System Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:17 15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'hypertension'	Junlin Long (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:39
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:11:48
Signature has been broken.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:11:38
User entered '5' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:11:38
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:46:20
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 20:08:13
User entered '1'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	Junlin Long	29 Jan 2021 14:11:38
User entered 'mg (mg)' reason for change: Per Query Resolution	Junlin Long	29 Jan 2021 14:11:38
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'tablet (TABLET)'	Junlin Long	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (ORAL)'	Junlin Long	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:51:54

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:54:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:54:30
Data point term sent to Coder	System	15 Oct 2020 17:53:18
User entered 'vitamin b12'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'prophylaxis supplement'	Junlin Long (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 03:24:37
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'dosage unknown; updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:07:53
Signature has been broken.	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:07:24
User entered 'unknown' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	24 Feb 2021 13:07:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:46:45
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 20:08:13
User entered '1'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	Junlin Long	24 Feb 2021 13:07:24
User entered 'Other (OTHER)' reason for change: Per Query Resolution	Junlin Long	24 Feb 2021 13:07:24
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'tablet (TABLET)'	Junlin Long	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	Junlin Long	24 Feb 2021 13:07:24
User entered 'unknown' reason for change: Per Query Resolution	Junlin Long	24 Feb 2021 13:07:24
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (ORAL)'	Junlin Long	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 17:52:25

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	15 Oct 2020 17:55:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 17:55:37
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 17:54:20
User entered 'flu vaccine'	Junlin Long (b) (4)	15 Oct 2020 17:53:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'prophylaxis for flu'	Junlin Long (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Other (OTHER)'	Junlin Long (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'injection'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:12:32
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	29 Jan 2021 14:12:32
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'other (OTHER)'	(b) (4)	
	Junlin Long (b) (4)	15 Oct 2020 17:53:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:12:32
User entered empty; reason for change Data Entry Error	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:12:32
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
	(b) (4)	
User entered 'yearly'	Junlin Long (b) (4)	15 Oct 2020 17:53:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Junlin Long (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '1 Sep 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '1 Sep 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
User entered empty.	System	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
User entered empty.	System	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:00
User entered empty.	System	15 Oct 2020 17:53:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 17:55:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 17:55:37
Data point term sent to Coder	System	15 Oct 2020 17:54:21
User entered 'vitamin d'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'prophylaxis supplement'	Junlin Long (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:29
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:13:12
Signature has been broken.	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:13:06
User entered '50000' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:13:06
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 06:47:08
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	15 Oct 2020 20:08:13
User entered '1'	Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	Junlin Long	29 Jan 2021 14:13:06
User entered 'IU (IU)' reason for change: Per Query Resolution	Junlin Long	29 Jan 2021 14:13:06
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'tablet (TABLET)'	Junlin Long	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
Signature has been broken.	Junlin Long	29 Jan 2021 14:13:06
User entered 'every week (QS)' reason for change:	Junlin Long	29 Jan 2021 14:13:06
Data Entry Error		
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'once daily (QD)'	Junlin Long	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'un UNK 2020'	Junlin Long (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered '0'	Junlin Long	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered empty.	Junlin Long	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:08:13
User entered 'No (N)'	Junlin Long (b) (4)	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	29 Jan 2021 14:13:06
User entered '804 (804)'	System	15 Oct 2020 17:54:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User closed query 'Per DM CLR: Con Med MELATONIN was added/changed on 25 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 04:24:48
Query 'Per DM CLR: Con Med MELATONIN was added/changed on 25 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'participant reported taking this medication for prophylaxis.' (Site from DM).	Junlin Long (b) (4) (b) (4)	01 Mar 2021 16:11:10
User opened query 'Per DM CLR: Con Med MELATONIN was added/changed on 25 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:48:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 14:15:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 14:15:18
Data point term sent to Coder	System	29 Jan 2021 14:14:21
User entered 'melatonin'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'insomnia'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '10'	Junlin Long	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '25 Jan 2021'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	Junlin Long (b) (4)	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 14:14:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 15:16:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 15:16:30
Data point term sent to Coder	System	29 Jan 2021 14:15:22
User entered 'protonix'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'prevent gerd'	Junlin Long (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '40'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:14:59
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'twice daily (BID)'	Junlin Long (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:14:59
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:14:59
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
User entered '2'	System	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
User entered '1'	System	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:06
User entered '804 (804)'	System	29 Jan 2021 14:14:59

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON, PARENTERAL PREPARATIONS, PRODUCT: SACCHARATED IRON OXIDE, PRODUCTSYNONYM: VENOFER - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 12:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 12:31:43
Data point term sent to Coder	System	29 Jan 2021 14:16:22
User entered 'venofir'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'anemia'	Junlin Long (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '200'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:15:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:15:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Intravenous (INTRAVENOUS)'	Junlin Long (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:15:34
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
User entered '1'	System	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
User entered '1'	System	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:10
User entered '804 (804)'	System	29 Jan 2021 14:15:34

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 14:17:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 14:17:18
Data point term sent to Coder	System	29 Jan 2021 14:16:22
User entered 'ativan'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'insomnia'	Junlin Long (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '1'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:16:11
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'once (ONCE)'	Junlin Long (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:16:11
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:16:11
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '13 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '13 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
User entered empty.	System	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
User entered empty.	System	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:15
User entered empty.	System	29 Jan 2021 14:16:11

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 14:19:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 14:19:23
Data point term sent to Coder	System	29 Jan 2021 14:18:23
User entered 'tylenol'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'prevention of fever'	Junlin Long (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '650'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:18:03
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'as needed (PRN)'	Junlin Long (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:18:03
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Oral (ORAL)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:18:03
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
User entered empty.	System	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
User entered empty.	System	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:19
User entered empty.	System	29 Jan 2021 14:18:03

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Jan 2021 14:20:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 14:20:34
Data point term sent to Coder	System	29 Jan 2021 14:19:34
User entered 'vitamin b12'	Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	Junlin Long (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'anemia'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '1000'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'ug (ug)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:19:09
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'once daily (QD)'	Junlin Long (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:19:09
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Junlin Long (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:19:09
	(b) (4)	

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	Junlin Long (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
User entered '1'	System	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
User entered '1'	System	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:23
User entered '804 (804)'	System	29 Jan 2021 14:19:09

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 08:57:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 08:57:59
Data point term sent to Coder	System	03 Mar 2021 14:03:44
User entered 'IBUPROFEN'	(b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'RIB CAGE PAIN'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '400'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:19:35
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable' answered with 'updated. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:39:43
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 11:39:01
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 11:39:01
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 11:39:01
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 11:39:01
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 11:39:01
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 11:39:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:59
User closed query "'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' ' (Site from DM). Query "'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:20:03
	(b) (4), (b) (6)	07 Apr 2021 12:37:34
	(b) (4), (b) (6)	07 Apr 2021 12:37:29
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 12:37:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 12:37:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query "'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.'" ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 09:35:59
	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User entered empty.	System	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User entered empty.	System	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:30
User entered empty.	System	03 Mar 2021 14:03:04

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:41:52
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 Apr 2021 17:41:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	05 Mar 2021 21:58:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 00:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 00:19:46
Data point term sent to Coder	System	03 Mar 2021 14:05:45
User entered '0.9% NaCL'	(b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'anemia'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'continuous'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	03 Mar 2021 14:05:22
User entered '01 Jan 2021'	(b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:42:48
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
User entered empty.	System	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
User entered empty.	System	03 Mar 2021 14:05:02

US3622197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:35
User entered empty.	System	03 Mar 2021 14:05:02

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:15:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:59:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:30
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Jan 2021 14:19:40

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '12 Jan 2021'	Junlin Long (b) (4)	29 Jan 2021 14:20:11

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'chest x-ray'	Junlin Long (b) (4)	29 Jan 2021 14:20:11

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	29 Jan 2021 14:20:11

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:20:11

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '12 Jan 2021'	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:20:26
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'ekg'	Junlin Long (b) (4)	29 Jan 2021 14:20:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Diagnostic (DIAGNOSTIC)'	Junlin Long (b) (4)	29 Jan 2021 14:20:26

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:20:26
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '13 Jan 2021'	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:21:19
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'blood transfusion (2 units of prbs's)'	Junlin Long (b) (4)	29 Jan 2021 14:21:19

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Adverse Event (AE)'	Junlin Long (b) (4)	29 Jan 2021 14:21:19

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:21:19
	(b) (4)	

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '15 Jan 2021'	(b) (4) Junlin Long (b) (4) (b) (4)	29 Jan 2021 14:22:39

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'blood transfusion (1 unit of prbc)'	Junlin Long (b) (4)	29 Jan 2021 14:22:39

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered 'Adverse Event (AE)'	Junlin Long (b) (4)	29 Jan 2021 14:22:39

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	29 Jan 2021 14:22:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:55:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'cbc lab'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:55:26

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:55:26

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:56:20

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'FOBT'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:56:20

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:56:20

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:38:57
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:36

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'IRON LAB'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:36

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:36

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:56

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'TIBC LAB'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:56

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:57:56

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:15:34

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:58:19

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'IRON SATURATION LAB'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:58:19

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 13:58:19

US3622197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:15:34

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:39:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:41:13
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:58:13
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'USA-US085-2021-MRNA-1273-P301000002'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Susanne'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Doblecki-Lewis'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '1120 NW 14th Street'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Miami'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'FL'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '33136'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'US'	(b) (4) System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
	(b) (4)	
Signature has been broken.	System	29 Jan 2021 15:39:18
User entered '2'	System	29 Jan 2021 15:39:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
	(b) (4)	
User entered '1'	System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'USA-US085-2021-MRNA-1273-P301000002'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Susanne'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Doblecki-Lewis'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '1120 NW 14th Street'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Miami'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'FL'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '33136'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'US'	(b) (4) System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
	(b) (4)	
Signature has been broken.	System	29 Jan 2021 15:39:18
User entered '2'	System	29 Jan 2021 15:39:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
	(b) (4)	
User entered '1'	System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:15:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered '13/Jan/2021 23:39'	(b) (4) System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:15:34

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered '1'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'USA-US085-2021-MRNA-1273-P301000002'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Yes (Y)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'No (N)'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Susanne'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Doblecki-Lewis'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '1120 NW 14th Street'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'Miami'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered 'FL'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:38:31
User entered '33136'	System	13 Jan 2021 23:38:06

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
User entered 'US'	(b) (4) System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:15:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
	(b) (4)	
Signature has been broken.	System	29 Jan 2021 15:39:18
User entered '2'	System	29 Jan 2021 15:39:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:08:16
	(b) (4)	
User entered '1'	System	13 Jan 2021 23:39:22

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:15:34

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '29/Jan/2021 10:39'	(b) (4) System	29 Jan 2021 15:39:18

US3622197

Folder: SAE USA-US085-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:15:34

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 11:24:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:07:03
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 15:39:18