

US3172119 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:30:08

All time stamps listed in this document are displayed in GMT

US3172119

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:31:17

Generated On: 09 Jun 2021 15:30:08

Participant ID

US3172119

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

US3172119

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 AUG 2020

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

Folder OID SCRN

US3172119

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	False
Not reported	False

US3172119

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Date of Informed Consent (*dd MMM yyyy*) 14 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3172119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Did the participant meet all eligibility criteria?

Yes

No

US3172119

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Were any significant conditions reported?

Yes

No

US3172119

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	HEPARIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	LOVANOX ALLERGY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	LEFT LEG FRACTURE PIN PLACED SURGERY
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3172119

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	LEFT LEG FRACTURE
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3172119

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	BILATERAL SENSORIAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3172119

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	CHRONIC DIFFUSE OTITIS EXTERNA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3172119

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	INCREASED CERUMEN PRODUCTION
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3172119

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE - COPD
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	GASTROESOPHAGEAL REFLUX DISEASE - GERD
Start date (dd MMM yyyy)	12 JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3172119

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172119

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3172119

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 14 AUG 2020

Time of assessment (00:00-23:59) 12:52 (24 HR)

Vital Signs Date and Time (derived) 14 AUG 2020 12:52

Height (xxx.x) 155.4 cm

Weight (xxx.x) 53.0 kg

BMI (xxx.x) 21.94693 kg/m²

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3172119

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

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.

US3172119

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*) 14 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2000

Date of last menstruation unknown False

US3172119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3172119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

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	

US3172119

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 AUG 2020

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

Folder OID VISIT1

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

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

What was the participant's randomization number? 186402

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

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:52 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:52
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:49 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 15:49
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	52 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 AUG 2020

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

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:17 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 15:17

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

What was the frequency of the study treatment dosing? ONCE

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

US3172119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 14 AUG 2020

Collection time (*00:00-23:59*) 14:44 (24 HR)

Collection date and time (derived) 14 AUG 2020 14:44

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Collection date (<i>dd MMM yyyy</i>)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	14 AUG 2020 14:40
Nasopharyngeal Swab 2	No		

US3172119

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 14 AUG 2020 16:29

PC Open Date & Time 14 AUG 2020 15:37

PC Close Date & Time 14 AUG 2020 18:07

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 97.1 °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 14 AUG 2020 19:05
PC Open Date & Time 14 AUG 2020 19:02
PC Close Date & Time 15 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 12:12
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 16 AUG 2020 12:00
PC Close Date & Time 17 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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
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 17 AUG 2020 12:00
PC Close Date & Time 18 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 AUG 2020 09:22
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 97.1 °F

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

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

PC Time Stamp	19 AUG 2020 13:24
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 AUG 2020 16:03
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	14 AUG 2020 16:30
PC Open Date & Time	14 AUG 2020 15:37
PC Close Date & Time	14 AUG 2020 18:07

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

14 AUG 2020 19:06

PC Open Date & Time

14 AUG 2020 19:02

PC Close Date & Time

15 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 2

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 AUG 2020 12:13
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 3

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

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 4

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

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 5

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	19 AUG 2020 09:23
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 6

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

19 AUG 2020 13:24

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 7

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

20 AUG 2020 16:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

No

Yes

PC Time stamp	14 AUG 2020 16:31
PC Open Date & Time	14 AUG 2020 15:37
PC Close Date & Time	14 AUG 2020 18:07

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

No
Yes

PC Time stamp	14 AUG 2020 19:07
PC Open Date & Time	14 AUG 2020 19:02
PC Close Date & Time	15 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp	15 AUG 2020 12:14
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp	19 AUG 2020 09:23
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

	Yes <input type="checkbox"/>
PC Time stamp	19 AUG 2020 13:25
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 16:04
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3172119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 SEP 2020

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

Folder OID VISIT2

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:08 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:08
Temperature (<i>xxx.x</i>)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:32 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:32
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:02 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:02

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

US3172119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 11 SEP 2020

Collection time (*00:00-23:59*) 12:39 (24 HR)

Collection date and time (derived) 11 SEP 2020 12:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:33	11 SEP 2020 12:33
Nasopharyngeal Swab 2	No		

US3172119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 97.0 °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 11 SEP 2020 13:23

PC Open Date & Time 11 SEP 2020 13:22

PC Close Date & Time 11 SEP 2020 15:52

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp 11 SEP 2020 17:33
PC Open Date & Time 11 SEP 2020 16:47
PC Close Date & Time 12 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 _____

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 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F _____
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 13 SEP 2020 12:00
PC Close Date & Time 14 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 _____
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 14 SEP 2020 12:00
PC Close Date & Time 15 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

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**

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 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

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
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 16 SEP 2020 12:00
PC Close Date & Time 17 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 20:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

11 SEP 2020 13:24

PC Open Date & Time

11 SEP 2020 13:22

PC Close Date & Time

11 SEP 2020 15:52

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

11 SEP 2020 17:34

PC Open Date & Time

11 SEP 2020 16:47

PC Close Date & Time

12 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 2

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

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 3

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

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 4

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

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 5

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 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 6

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

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 7

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 20:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

No

Yes

PC Time stamp	11 SEP 2020 13:25
PC Open Date & Time	11 SEP 2020 13:22
PC Close Date & Time	11 SEP 2020 15:52

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

No

Yes

PC Time stamp	11 SEP 2020 17:35
PC Open Date & Time	11 SEP 2020 16:47
PC Close Date & Time	12 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

Yes

PC Time stamp	17 SEP 2020 20:50
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3172119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:31:25

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 09 OCT 2020

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

Folder OID VISIT3

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:31:25

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:52 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 10:52
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3172119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:31:25

Generated On: 09 Jun 2021 15:30:08

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.

US3172119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:31:25

Generated On: 09 Jun 2021 15:30:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	09 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:10 (24 HR)
Collection date and time (derived)	09 OCT 2020 11:10

US3172119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 117

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

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

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#) 10 DEC 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 12:49:25
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 18:07:01
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 17:58:22
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 18:22:40
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 MAR 2021 20:36:08
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 10:17:06
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 09:09:15
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 09:44:40
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 15:09:43
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 APR 2021 14:44:58
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#) 18 NOV 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#) 09 DEC 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	03 MAR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	31 MAR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#) 19 MAY 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#) 18 AUG 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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°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

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3172119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:30:08

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		10 MAR 2021 20:27:40

US3172119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

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 MISSED OPEN LABEL

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:06:11

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 MAR 2021

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

Folder OID VISIT4

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:06:11

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 29 MAR 2021

Time of assessment (00:00-23:59) 08:48 (24 HR)

Vital Signs Date and Time (derived) 29 MAR 2021 08:48

Temperature (xxx.x) 37.1 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 83 beats/min

Pulse units BPM

Respiratory Rate (xxx) 13 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 91 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 62 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3172119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:06:11

Generated On: 09 Jun 2021 15:30:08

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.

US3172119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:06:11

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

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

Collection date and time (derived) _____

US3172119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:06:11

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

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 _____

US3172119

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3172119

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:30:08

Generate Next COVID-19 Assessment

Yes

No

US3172119

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 22 JAN 2021

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

Folder OID UNBLND_DECIDE

US3172119

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3172119

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3172119

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 12:00
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 14:36
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:31:19

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3172119

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:31:19

Generated On: 09 Jun 2021 15:30:08

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 14:06 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 14:06

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

US3172119

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:31:19

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 JAN 2021

Collection time (*00:00-23:59*) 13:25 (24 HR)

Collection date and time (derived) 22 JAN 2021 13:25

US3172119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 15:31:18

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 JAN 2021

Collection time (*00:00 - 23:59*) 13:26

Collection Date and Time (derived) 22 JAN 2021 13:26

US3172119

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:19

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:31:24

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit? Yes
No

Continuing Flag 1

OLD29 Placebo Flag 1

US3172119

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 MAR 2021

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

Folder OID OLD29

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 09:00
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	02 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 12:20
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	96 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3172119

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3172119

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 02 MAR 2021

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 02 MAR 2021 11:50

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

US3172119

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 20:10:58

Generated On: 09 Jun 2021 15:30:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172119

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 29 MAR 2021

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

Folder OID OLD57

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 29 MAR 2021

Time of assessment (00:00-23:59) 08:48 (24 HR)

Vital Signs Date and Time (derived) 29 MAR 2021 08:48

Temperature (xxx.x) 37.1 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 83 beats/min

Pulse units BPM

Respiratory Rate (xxx) 13 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 91 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 62 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3172119

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

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.

US3172119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 29 MAR 2021

Collection time (*00:00-23:59*) 09:36 (24 HR)

Collection date and time (derived) 29 MAR 2021 09:36

US3172119

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Mar 2021 13:51:21

Generated On: 09 Jun 2021 15:30:08

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

AEID USA-US118-2021-MRNA-1273-P30
1000009

Adverse event LEFT SIDE RIB CAGE MULTIPLE
FRACTURE

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) 09 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) _____

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) 09 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 12 FEB 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

PRODUCTION RELEASE (v12.003 374 of 2576
EAB) (1725)

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

SUBJECT CAME IN TODAY FOR
29 VISIT OPEN LABEL. SHE
REPORTED SHE WENT TO THE
ER ON 9FEB2021 IN VM
HOSPITAL, WHERE SHE WAS
ADMITTED AFTER FALL AND
BROKE HER LEFT SIDE RIB
CAGE MULTIPLE FRACTURE.
NEW MEDS WAS ORDERED.
MEDICAL RECORDS WILL BE
REQUESTED TO UPDATE SAE
AND FOLLOW UP.
SUBJECT WAS ADMITTED AT
UM HOSPITAL ON 09FEB2021
THROUGH 12FEB2021 AFTER
MOTOR VEHICLE ACCIDENT
WHILE SHE WAS RIDING A
SCOOTER AND WAS WAS HIT
BY THE BACK BY A CAR. C/O
LEFT SIDE RIB PAIN: SHE WAS
FOUND TO HAVE 4 POSTERIOR
RIB FRACTURE AND WAS
ADMITTED FOR PAIN CONTROL
GIVEN EXCRUCIATING PAIN
THAT WAS TREATMENT WITH
BLOCK BY ANESTHESIA AND
HER PAIN IMPROVED
SUBSTANTIALLY. DUE TO PAIN
EXACERBATION SHE WENT
BACK TO THE HOSPITAL ON
19FEB2021 THROUGH 21FEB2021
FOR 2 DAYS. CT WAS
PERFORMED WITHOUT
CONTRAST SHOW.
PROCEDURE DONE: CHEST
TRAUMA MINOR. FRACTURE
OF THE POSTERIOR LATERAL

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

SEVERTH THROUGH TEN RIB.
PARTIAL CALCIFIED NODULE
SEE IN LEFT THYROID LOBE
0.6CM. EMPHYSEMATOUS
LUNG CHANGES. SUBJECT WAS
DISCHARGED HOME WITH
ORAL MEDICATION. SUBJECT
WAS DISCHARGED ON STABLE
CONDITION AND PAIN WAS
CONTROLLED. THIS
ADMISSION WAS RELATED TO
THE MAIN SAE DUE TO RIB
PAIN EXACERBATION
RELATED TO RIB TRAUMA.
SUBJECT IS COMPLETELY
RECOVERED AS PER SUBJECT
REPORT BY PHONE CALLS. NO
FOLLOW UP HAS BEEN DONE
BY PCP DUE TO SUBJECT DOES
NOT HAVE A PCP.
LABORATORY RESULT WAS
REVIEWED EXCEPT FOR
HEPATITIS C . HCV, RNA, QQN,
PCR ABNORMAL/NCS. SUBJECT
RECOVERED FROM THE EVENT
AND CURRENTLY
ASYMPTOMATIC.

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

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

AEID USA-US118-2021-MRNA-1273-P30
1000009

Adverse event LEFT PLEURAL EFFUSION
SECONDARY TO LEFT RIB
FRACTURE

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) 19 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) _____

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) 19 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 21 FEB 2021

Admitted to ICU? Yes
No
Unknown

PRODUCTION RELEASE (v12.003 378 of 2576
EAB) (1725)

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

ON PHONE CALL TO FOLLOW UP, SUBJECT TODAY REPORTED THAT THEY WERE ADMITTED AT UM HOSPITAL ON 19FEB 2021 THROUGH 21FEB2021 FOR EXACERBATION OF PAIR RIB AND WAS DIAGNOSED WITH LEFT PLEURAL EFFUSION SECONDARY TO LEFT RIB FRACTURE. SUBJECT WAS DISCHARGED HOME WITH ORAL MEDICATION. PENDING MEDICAL RECORD RECORDS.

SUBJECT WAS ADMITTED AT UM HOSPITAL ON 09FEB2021 THROUGH 12FEB2021 AFTER MOTOR VEHICLE ACCIDENT WHILE SHE WAS RIDING A SCOOTER AND WAS WAS HIT BY THE BACK BY A CAR. C/O LEFT SIDE RIB PAIN: SHE WAS FOUND TO HAVE 4 POSTERIOR RIB FRACTURE AND WAS ADMITTED FOR PAIN CONTROL GIVEN EXCRUCIATING PAIN THAT WAS TREATMENT WITH BLOCK BY ANESTHESIA AND HER PAIN IMPROVED SUBSTANTIALLY. DUE TO PAIN EXACERBATION SHE WENT BACK TO THE HOSPITAL ON 19FEB2021 THROUGH 21FEB2021 FOR 2 DAYS. CT WAS PERFORMED WITHOUT CONTRAST SHOW.

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

PROCEDURE DONE: CHEST
TRAUMA MINOR. FRACTURE
OF THE POSTERIOR LATERAL
SEVENTH THROUGH TEN RIB.
PARTIAL CALCIFIED NODULE
SEE IN LEFT THYROID LOBE
0.6CM. EMPHYSEMATOUS
LUNG CHANGES. SUBJECT WAS
DISCHARGED HOME WITH
ORAL MEDICATION. SUBJECT
WAS DISCHARGED ON STABLE
CONDITION AND PAIN WAS
CONTROLLED. THIS
ADMISSION WAS RELATED TO
THE MAIN SAE DUE TO RIB
PAIN EXACERBATION
RELATED TO RIB TRAUMA.
SUBJECT IS COMPLETELY
RECOVERED AS PER SUBJECT
REPORT BY PHONE CALLS. NO
FOLLOW UP HAS BEEN DONE
BY PCP DUE TO SUBJECT DOES
NOT HAVE A PCP.
LABORATORY RESULT WAS
REVIEWED EXCEPT FOR
HEPATITIS C . HCV, RNA, QQN,
PCR ABNORMAL/NCS. SUBJECT
RECOVERED FROM THE EVENT
AND CURRENTLY
ASYMPTOMATIC.

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

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

AEID

Adverse event

LEFT THYROID NODE
PARTIALLY CALCIFIED

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)

09 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)

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2576

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:31:18

Generated On: 09 Jun 2021 15:30:08

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

Yes

No

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication PROPHYLAXIS

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)

385 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication FIBER (METHYLCELLULOSE)

Prophylaxis Yes
No

Indication CONSTIPATION

Dose per administration 0.52

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication CALCIUM

Prophylaxis Yes
No

Indication PROPHYLAXIS

Dose per administration 600

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication KETORALAC

Prophylaxis Yes
No

Indication LEFT RIB PAIN

Dose per administration 15

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MG/ML

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)

391 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 09 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 FEB 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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication OXYCODONE

Prophylaxis Yes
No

Indication LEFT RIB PAIN

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

PRN / EVERY 6 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 12 FEB 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) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication DICLOFENAC

Prophylaxis Yes
No

Indication LEFT RIB PAIN

Dose per administration 50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 12 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 19 FEB 2021

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication ALENDRONATE

Prophylaxis Yes
No

Indication OSTEOPOROSIS

Dose per administration 70

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)

397 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication ALPRAZOLAM

Prophylaxis Yes
No

Indication ANXIETY

Dose per administration 2

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)

399 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication SYMBICORT

Prophylaxis Yes
No

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE - COPD

Dose per administration 80/4.5

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication BUSPIRONE

Prophylaxis Yes
No

Indication ANXIETY

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)

403 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication REXULTI

Prophylaxis Yes
No

Indication MAJOR DEPRESSION

Dose per administration 2

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)

405 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2002

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) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication TRAZODONE

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 150

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)

407 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication PANTOPRAZOLE

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX
DISEASE - 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

409 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 12 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 14 FEB 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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication VENLAFAXINE

Prophylaxis Yes
No

Indication ANTI-DEPRESSANT

Dose per administration 150

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)

411 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2002

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

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication LIDOCAINE 700MG, 50MG X
GRAM ADHESIVE

Prophylaxis Yes
No

Indication LEFT SIDE RIB PAIN

Dose per administration 750

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

413 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	19 FEB 2021
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication VOLTANEN

Prophylaxis Yes
No

Indication LEFT SIDE RIB PAIN

Dose per administration 1.16

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)

415 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 19 FEB 2019

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) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Name of Medication ACETAMINOPHEN

Prophylaxis Yes
No

Indication LEFT SIDE RIB PAIN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 16:06:09

Generated On: 09 Jun 2021 15:30:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 19 FEB 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) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:31:18

Generated On: 09 Jun 2021 15:30:08

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3172119

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:30:08

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

- AE (specify)
- SAE (specify)
- Death
- Lost To Follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation (specify)
- Study Terminated By Sponsor
- Withdrawal of consent by participant (specify)
- Due to SARS-COV-2
- Other

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

US3172119

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:30:08

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

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P30 1000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:16
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

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	04/MAR/2021 08:51
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.	<input checked="" type="checkbox"/> True

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:09
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.	<input checked="" type="checkbox"/> True

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/MAR/2021 18:07
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.	<input checked="" type="checkbox"/> True

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 16:06:10

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/MAR/2021 08:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 16 Mar 2021 17:57:06

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P30 1000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Mar 2021 17:57:06

Generated On: 09 Jun 2021 15:30:08

SAEID	USA-US118-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	16/MAR/2021 10:15
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.	<input checked="" type="checkbox"/> True

Audit

US3172119 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172119

Form: Participant Creation

Generated On: 09 Jun 2021 15:30:08

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'US3172119'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:09:38

US3172119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 20:19:41

US3172119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:09:39

US3172119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 20:19:41

US3172119

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'SCRN'	System	14 Aug 2020 20:19:41

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:09:40

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '66'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'YEARS'	System	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '66'	System	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Female (F)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:25:13
User entered 'Male (M)'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:30:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 20:19:53

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Aug 2020'	System	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2020'	System	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:04

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:09:39

US3172119

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:30:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '1'	System	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:30:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:15

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:29:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:29:13
Data point term sent to Coder	System	17 Aug 2020 15:27:49
User entered 'PRESBYOPIA'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2000'	System	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2000'	System	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:27:44

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:32:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:32:20
Data point term sent to Coder	System	17 Aug 2020 15:30:59
User entered 'CONSTIPATION'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2015'	System	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2015'	System	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:30:57

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User closed query 'Per DM CLR: Please review this Condition and please note that this information should be reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:55:55
Query 'Per DM CLR: Please review this Condition and please note that this information should be reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:49
User opened query 'Per DM CLR: Please review this Condition and please note that this information should be reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 19:05:17
User coded data point as SOC: Social circumstances, HLG: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:33:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 15:33:19
Data point term sent to Coder	System	17 Aug 2020 15:32:03
User entered 'POSTMENOPAUSAL'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2000'	System	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2000'	System	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:23

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:56:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:56:15
Data point term sent to Coder System	System	17 Aug 2020 15:32:03
User entered 'HEPARIN ALLERGY'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2007'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:38

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:08:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:08:14
Data point term sent to Coder System	System	17 Aug 2020 15:32:03
User entered 'LOVANOX ALLERGY'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2007'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	17 Aug 2020 15:31:58

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture treatment - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:36:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:36:38
Data point term sent to Coder	System	02 Sep 2020 12:18:53
User closed query 'For coding purposes, please split LEFT LEG FRACTURE PIN PLACED SURGERY into separate entries. 1. LEFT LEG FRACTURE and 2. LEFT LEG FRACTURE PIN PLACED SURGERY' (Site from System).	System	02 Sep 2020 12:18:32
Query 'For coding purposes, please split LEFT LEG FRACTURE PIN PLACED SURGERY into separate entries. 1. LEFT LEG FRACTURE and 2. LEFT LEG FRACTURE PIN PLACED SURGERY' answered with 'Data entered' (Site from System).	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:32
User opened query 'For coding purposes, please split LEFT LEG FRACTURE PIN PLACED SURGERY into separate entries. 1. LEFT LEG FRACTURE and 2. LEFT LEG FRACTURE PIN PLACED SURGERY' (Site from System).	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:59:31
Data point term sent to Coder	System	17 Aug 2020 15:33:05
User entered 'LEFT LEG FRACTURE PIN PLACED SURGERY'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2007'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'UN UNK 2007'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	17 Aug 2020 15:32:22

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLGTT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Leg fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:55:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:55:48
Data point term sent to Coder	System	02 Sep 2020 12:19:53
User entered 'LEFT LEG FRACTURE'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'un UNK 2007'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'un UNK 2007'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2007'	System	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2007'	System	02 Sep 2020 12:18:58

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:57:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:57:06
Data point term sent to Coder	System	13 Apr 2021 13:55:38
User entered 'headache'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2018'	System	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2018'	System	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:55:04

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness neurosensory, LLT: Sensorineural hearing loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:59:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 07:59:46
Data point term sent to Coder	System	13 Apr 2021 13:56:39
User entered 'bilateral sensorial hearing loss'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:56:15

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis externa, LLT: Otitis externa - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:59:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:59:49
Data point term sent to Coder	System	13 Apr 2021 13:59:43
User entered 'chronic diffuse otitis externa'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 13:59:34

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Ear and labyrinth disorders, HLGT: External ear disorders (excl congenital), HLT: External ear disorders NEC, PT: Excessive cerumen production, LLT: Excessive cerumen production - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:35:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:35:41
Data point term sent to Coder	System	13 Apr 2021 14:01:45
User entered 'increased cerumen production'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:00:54

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:04:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:04:00
Data point term sent to Coder	System	13 Apr 2021 14:02:46
User entered 'Chronic obstructive pulmonary disease - COPD'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:01:50

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:04:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:04:01
Data point term sent to Coder	System	13 Apr 2021 14:02:46
User entered 'Gastroesophageal reflux disease - gerd'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:35:47
User entered '12 Jan 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:35:47
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:03:17
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:03:17
User entered '12 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:17
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:02:59
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:02:59
User entered '02 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:59
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	13 Apr 2021 14:02:42
User entered '12 Jan 2021'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2020'	System	13 Apr 2021 14:35:47
User entered 'Jan 2021'	System	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2020'	System	13 Apr 2021 14:35:47
User entered '2021'	System	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:02:42

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:06:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:06:00
Data point term sent to Coder	System	13 Apr 2021 14:04:48
User entered 'hepatitis c'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2018'	System	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2018'	System	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:03:58

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:05
Data point term sent to Coder	System	13 Apr 2021 14:05:48
User entered 'osteoporosis'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:04:50

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:06
Data point term sent to Coder	System	13 Apr 2021 14:05:48
User entered 'anxiety'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:15

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:07:05
Data point term sent to Coder	System	13 Apr 2021 14:05:48
User entered 'depression'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:26

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as SOC: Psychiatric disorders, HLT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:08:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:08:08
Data point term sent to Coder	System	13 Apr 2021 14:06:49
User entered 'bipolar disorder'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'Jan 2002'	System	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '2002'	System	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered empty.	System	13 Apr 2021 14:05:54

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:52'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered '14 Aug 2020 12:52'	System	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '155.4' cm	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35
DataPoint set to visible.	System	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '53.0' kg	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35
DataPoint set to visible.	System	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
Amendment Manager: User entered '21.94693'	System	16 Sep 2020 23:57:39
User entered '21.9'	System	17 Aug 2020 14:45:35
DataPoint set to visible.	System	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'kg/m2'	System	17 Aug 2020 14:45:35
DataPoint set to visible.	System	14 Aug 2020 20:20:08

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 11:14:42
Query 'Data is required. Please provide.' answered with 'per guidelines, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 21:18:31
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 14:45:35
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'bpm'	System	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'breaths/min'	System	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'mmHg'	System	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User entered 'mmHg'	System	17 Aug 2020 14:45:35

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28

US3172119

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28

US3172119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:15:52
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:44:46

US3172119

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:15:52
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 14:36:38
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 17:14:24
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:44:46

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'un UNK 2000'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:30:08

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 20:26:30

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'RETIRED'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '1'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '0'	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:30:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	17 Aug 2020 14:42:50

US3172119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 20:20:18

US3172119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 20:20:18

US3172119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 20:20:18

US3172119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'VISIT1'	System	14 Aug 2020 20:20:18

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:19:50

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:37:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:37:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:19:50
User entered '186402' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:19:50

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:19:50

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:25

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:25

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:25

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:25

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:25

US3172119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:21:21

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:52'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '14 Aug 2020 12:52'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '75'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'bpm'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'breaths/min'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '100'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 18:12:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Abnormal, NCS' (Site from System).	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 21:15:45
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:57:39
User entered '55'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:37:26
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 12:03:42
User entered '15:49'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '14 Aug 2020 15:49'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.3' C	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '52'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'bpm'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '16'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'breaths/min'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '121'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '77'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	18 Aug 2020 12:03:42

US3172119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:16:04
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:47

US3172119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:16:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:03:47

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Aug 2020 20:20:55
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	14 Aug 2020 20:20:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 20:20:55
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	14 Aug 2020 20:20:48
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Aug 2020 20:20:55
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Aug 2020 20:20:48
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 20:20:55
User entered empty.	System	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '15:17'	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '14 Aug 2020 15:17'	System	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'ONCE'	System	14 Aug 2020 20:20:55
User entered empty.	System	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 20:20:55
User entered empty.	System	14 Aug 2020 20:20:48

US3172119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:03

US3172119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:03

US3172119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14:44'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:03

US3172119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '14 Aug 2020 14:44'	System	18 Aug 2020 12:04:03

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:30:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14:40'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '14 Aug 2020 14:40'	System	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:03:56
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:03:56
User entered '14:40'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered empty.	System	17 Sep 2020 13:03:56
User entered '14 Aug 2020 14:40'	System	18 Aug 2020 12:04:22

US3172119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:26

US3172119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	18 Aug 2020 12:04:26

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:28:39', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '38ef2894-4df2-423a-b887-63287e24486b'	System	14 Aug 2020 20:29:58
User entered 'Yes (Y)'	System	14 Aug 2020 20:29:58

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:01', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '38ef2894-4df2-423a-b887-63287e24486b'	System	14 Aug 2020 20:29:58
User entered '98.6'	System	14 Aug 2020 20:29:58

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '38ef2894-4df2-423a-b887-63287e24486b'	System	14 Aug 2020 20:29:58
User entered 'No (N)'	System	14 Aug 2020 20:29:58

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:19', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '38ef2894-4df2-423a-b887-63287e24486b'	System	14 Aug 2020 20:29:58
User entered '14 Aug 2020 16:29'	System	14 Aug 2020 20:29:58

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 15:37'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 18:07'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:05:15', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f85bb97d-60bd-4324-9ea1-514164027522'	System	14 Aug 2020 23:06:26
User entered 'Yes (Y)'	System	14 Aug 2020 23:06:26

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:05:32', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f85bb97d-60bd-4324-9ea1-514164027522'	System	14 Aug 2020 23:06:26
User entered '97.1'	System	14 Aug 2020 23:06:26

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:05:39', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f85bb97d-60bd-4324-9ea1-514164027522'	System	14 Aug 2020 23:06:26
User entered 'No (N)'	System	14 Aug 2020 23:06:26

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:05:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f85bb97d-60bd-4324-9ea1-514164027522'	System	14 Aug 2020 23:06:26
User entered '14 Aug 2020 19:05'	System	14 Aug 2020 23:06:26

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 19:02'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 2'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:12:25', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'df707812-e660-445b-b1b6-b33824ce6354'	System	15 Aug 2020 16:13:32
User entered 'Yes (Y)'	System	15 Aug 2020 16:13:32

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:12:37', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'df707812-e660-445b-b1b6-b33824ce6354'	System	15 Aug 2020 16:13:32
User entered '98.2'	System	15 Aug 2020 16:13:32

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:12:43', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'df707812-e660-445b-b1b6-b33824ce6354'	System	15 Aug 2020 16:13:32
User entered 'No (N)'	System	15 Aug 2020 16:13:32

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:12:49', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'df707812-e660-445b-b1b6-b33824ce6354'	System	15 Aug 2020 16:13:32
User entered '15 Aug 2020 12:12'	System	15 Aug 2020 16:13:32

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 3'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 4'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 5'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:00', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0a2e4802-23e5-4550-952f-0cccc064ad02'	System	19 Aug 2020 13:23:19
User entered 'Yes (Y)'	System	19 Aug 2020 13:23:19

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:23', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0a2e4802-23e5-4550-952f-0cccc064ad02'	System	19 Aug 2020 13:23:19
User entered '96.2'	System	19 Aug 2020 13:23:19

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:29', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0a2e4802-23e5-4550-952f-0cccc064ad02'	System	19 Aug 2020 13:23:19
User entered 'No (N)'	System	19 Aug 2020 13:23:19

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:36', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0a2e4802-23e5-4550-952f-0cccc064ad02'	System	19 Aug 2020 13:23:19
User entered '19 Aug 2020 09:22'	System	19 Aug 2020 13:23:19

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 6'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:23:35', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4a5e53c8-fde7-4170-a49e-f7d0498a8efc'	System	19 Aug 2020 17:24:51
User entered 'Yes (Y)'	System	19 Aug 2020 17:24:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:23:50', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4a5e53c8-fde7-4170-a49e-f7d0498a8efc' User entered '97.1'	System	19 Aug 2020 17:24:51
	System	19 Aug 2020 17:24:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:23:55', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4a5e53c8-fde7-4170-a49e-f7d0498a8efc'	System	19 Aug 2020 17:24:51
User entered 'No (N)'	System	19 Aug 2020 17:24:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:07', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4a5e53c8-fde7-4170-a49e-f7d0498a8efc' User entered '19 Aug 2020 13:24'	System	19 Aug 2020 17:24:51
	System	19 Aug 2020 17:24:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 7'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:04', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '11471e0a-853f-4abb-a232-bc6f37c99a71'	System	20 Aug 2020 20:03:51
User entered 'Yes (Y)'	System	20 Aug 2020 20:03:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:02:29', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '11471e0a-853f-4abb-a232-bc6f37c99a71'	System	20 Aug 2020 20:03:51
User entered '96.2'	System	20 Aug 2020 20:03:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:02:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '11471e0a-853f-4abb-a232-bc6f37c99a71'	System	20 Aug 2020 20:03:51
User entered 'No (N)'	System	20 Aug 2020 20:03:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '11471e0a-853f-4abb-a232-bc6f37c99a71'	System	20 Aug 2020 20:03:51
User entered '20 Aug 2020 16:03'	System	20 Aug 2020 20:03:51

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:29', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60c0f123-d115-4305-b2d1-3c3583a4de06'	System	14 Aug 2020 20:30:59
User entered 'None (1)'	System	14 Aug 2020 20:30:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:38', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60c0f123-d115-4305-b2d1-3c3583a4de06'	System	14 Aug 2020 20:30:59
User entered 'No (N)'	System	14 Aug 2020 20:30:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60c0f123-d115-4305-b2d1-3c3583a4de06'	System	14 Aug 2020 20:30:59
User entered 'No (N)'	System	14 Aug 2020 20:30:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:29:56', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60c0f123-d115-4305-b2d1-3c3583a4de06'	System	14 Aug 2020 20:30:59
User entered 'None (1)'	System	14 Aug 2020 20:30:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:20', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60c0f123-d115-4305-b2d1-3c3583a4de06'	System	14 Aug 2020 20:30:59
User entered '14 Aug 2020 16:30'	System	14 Aug 2020 20:30:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 15:37'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 18:07'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:05:57', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60826b2b-816e-4ea5-a42d-c30849865a6f'	System	14 Aug 2020 23:06:59
User entered 'None (1)'	System	14 Aug 2020 23:06:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:03', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60826b2b-816e-4ea5-a42d-c30849865a6f'	System	14 Aug 2020 23:06:59
User entered 'No (N)'	System	14 Aug 2020 23:06:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:08', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60826b2b-816e-4ea5-a42d-c30849865a6f'	System	14 Aug 2020 23:06:59
User entered 'No (N)'	System	14 Aug 2020 23:06:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:15', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60826b2b-816e-4ea5-a42d-c30849865a6f'	System	14 Aug 2020 23:06:59
User entered 'None (1)'	System	14 Aug 2020 23:06:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:18', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '60826b2b-816e-4ea5-a42d-c30849865a6f' User entered '14 Aug 2020 19:06'	System	14 Aug 2020 23:06:59
	System	14 Aug 2020 23:06:59

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 19:02'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 2'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:12:59', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bfc533f9-e001-45a9-8eac-02b59c3200b0'	System	15 Aug 2020 16:13:55
User entered 'None (1)'	System	15 Aug 2020 16:13:55

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:03', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bfc533f9-e001-45a9-8eac-02b59c3200b0'	System	15 Aug 2020 16:13:55
User entered 'No (N)'	System	15 Aug 2020 16:13:55

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:08', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bfc533f9-e001-45a9-8eac-02b59c3200b0'	System	15 Aug 2020 16:13:55
User entered 'No (N)'	System	15 Aug 2020 16:13:55

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:13', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bfc533f9-e001-45a9-8eac-02b59c3200b0'	System	15 Aug 2020 16:13:55
User entered 'None (1)'	System	15 Aug 2020 16:13:55

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:16', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bfc533f9-e001-45a9-8eac-02b59c3200b0'	System	15 Aug 2020 16:13:55
User entered '15 Aug 2020 12:13'	System	15 Aug 2020 16:13:55

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 3'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 4'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 5'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:45', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '67e39276-8d61-44eb-817a-5e8a685a44b5'	System	19 Aug 2020 13:23:50
User entered 'None (1)'	System	19 Aug 2020 13:23:50

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '67e39276-8d61-44eb-817a-5e8a685a44b5'	System	19 Aug 2020 13:23:50
User entered 'No (N)'	System	19 Aug 2020 13:23:50

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:22:57', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '67e39276-8d61-44eb-817a-5e8a685a44b5'	System	19 Aug 2020 13:23:50
User entered 'No (N)'	System	19 Aug 2020 13:23:50

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:04', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '67e39276-8d61-44eb-817a-5e8a685a44b5'	System	19 Aug 2020 13:23:50
User entered 'None (1)'	System	19 Aug 2020 13:23:50

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '67e39276-8d61-44eb-817a-5e8a685a44b5'	System	19 Aug 2020 13:23:50
User entered '19 Aug 2020 09:23'	System	19 Aug 2020 13:23:50

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 6'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:14', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'd713b37a-04ae-47fd-b3a9-0ea4e90da00f'	System	19 Aug 2020 17:25:18
User entered 'None (1)'	System	19 Aug 2020 17:25:18

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:19', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'd713b37a-04ae-47fd-b3a9-0ea4e90da00f'	System	19 Aug 2020 17:25:18
User entered 'No (N)'	System	19 Aug 2020 17:25:18

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:26', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'd713b37a-04ae-47fd-b3a9-0ea4e90da00f'	System	19 Aug 2020 17:25:18
User entered 'No (N)'	System	19 Aug 2020 17:25:18

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:31', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'd713b37a-04ae-47fd-b3a9-0ea4e90da00f'	System	19 Aug 2020 17:25:18
User entered 'None (1)'	System	19 Aug 2020 17:25:18

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:38', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'd713b37a-04ae-47fd-b3a9-0ea4e90da00f'	System	19 Aug 2020 17:25:18
User entered '19 Aug 2020 13:24'	System	19 Aug 2020 17:25:18

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 7'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:18', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3dda7d5e-d5d6-44d1-8d7a-bf98c9f14716'	System	20 Aug 2020 20:04:44
User entered 'None (1)'	System	20 Aug 2020 20:04:44

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:25', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3dda7d5e-d5d6-44d1-8d7a-bf98c9f14716'	System	20 Aug 2020 20:04:44
User entered 'No (N)'	System	20 Aug 2020 20:04:44

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:31', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3dda7d5e-d5d6-44d1-8d7a-bf98c9f14716'	System	20 Aug 2020 20:04:44
User entered 'No (N)'	System	20 Aug 2020 20:04:44

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:35', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3dda7d5e-d5d6-44d1-8d7a-bf98c9f14716'	System	20 Aug 2020 20:04:44
User entered 'None (1)'	System	20 Aug 2020 20:04:44

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:03:52', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3dda7d5e-d5d6-44d1-8d7a-bf98c9f14716'	System	20 Aug 2020 20:04:44
User entered '20 Aug 2020 16:03'	System	20 Aug 2020 20:04:44

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:28', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:36', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:41', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:45', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:50', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:30:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'None (0)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:31:08', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered 'No (N)'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T16:31:13', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '85b8270f-2eb6-408d-95a0-01e28ac83f3b'	System	14 Aug 2020 20:31:52
User entered '14 Aug 2020 16:31'	System	14 Aug 2020 20:31:52

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 15:37'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 18:07'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:26', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:32', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:37', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:43', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:48', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:06:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'None (0)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:07:02', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered 'No (N)'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-14T19:07:09', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'c2f085c1-d2df-448a-9843-dd52df984b28'	System	14 Aug 2020 23:07:48
User entered '14 Aug 2020 19:07'	System	14 Aug 2020 23:07:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Aug 2020 19:02'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 2'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:23', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:28', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:33', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:38', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:42', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:13:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'None (0)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:14:06', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered 'No (N)'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-15T12:14:10', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3319932f-a2ef-4504-948c-ffa6fc40f337'	System	15 Aug 2020 16:14:49
User entered '15 Aug 2020 12:14'	System	15 Aug 2020 16:14:49

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 3'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 4'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 5'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:18', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:23', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:28', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:34', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:38', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:43', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'None (0)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:49', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f'	System	19 Aug 2020 13:24:34
User entered 'No (N)'	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T09:23:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '98785ec8-bae3-40f1-a028-24900c0d598f' User entered '19 Aug 2020 09:23'	System	19 Aug 2020 13:24:34
	System	19 Aug 2020 13:24:34

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 6'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:50', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:54', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:24:58', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:25:02', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:25:07', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'None (0)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:25:13', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered 'No (N)'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-19T13:25:19', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '1d1c5a74-019b-44f8-ab8f-592c3ba1bccb'	System	19 Aug 2020 17:25:59
User entered '19 Aug 2020 13:25'	System	19 Aug 2020 17:25:59

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 7'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:01', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:10', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:18', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:24', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:30', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:35', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'None (0)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered 'No (N)'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-08-20T16:04:45', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f45800df-74e6-4f0e-8def-82806e46fe40'	System	20 Aug 2020 20:05:25
User entered '20 Aug 2020 16:04'	System	20 Aug 2020 20:05:25

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 20:20:48

US3172119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:22:27

US3172119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '24 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:22:27

US3172119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:22:27

US3172119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:22:27

US3172119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:22:33

US3172119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'I'	System	31 Aug 2020 20:22:33

US3172119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:23:46

US3172119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '28 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:23:46

US3172119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:23:46

US3172119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:23:46

US3172119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 20:23:51

US3172119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	31 Aug 2020 20:23:51

US3172119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:38:24

US3172119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '04 Sep 2020'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:38:24

US3172119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:38:24

US3172119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:38:24

US3172119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 14:38:29

US3172119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	08 Sep 2020 14:38:29

US3172119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:14:24

US3172119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:14:24

US3172119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 17:14:24

US3172119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'VISIT2'	System	11 Sep 2020 17:14:24

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:08'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '11 Sep 2020 12:08'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '83'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'bpm'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '15'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'breaths/min'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '111'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '82'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '13:32'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '11 Sep 2020 13:32'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '63'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'bpm'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '16'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'breaths/min'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '105'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '61'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	15 Sep 2020 15:34:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:31:53

US3172119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:31:53

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '13:02'	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '11 Sep 2020 13:02'	System	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'ONCE'	System	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:14:39

US3172119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:39'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '11 Sep 2020 12:39'	System	15 Sep 2020 15:32:13

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:33'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '11 Sep 2020 12:33'	System	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:16:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 16:16:21
User entered '12:33'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered empty.	System	02 Oct 2020 16:16:21
User entered '11 Sep 2020 12:33'	System	15 Sep 2020 15:32:32

US3172119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Sep 2020 15:32:38

US3172119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	15 Sep 2020 15:32:38

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:22:17', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3bb0af75-32f1-4500-b502-c2ca6884815f'	System	11 Sep 2020 17:23:47
User entered 'Yes (Y)'	System	11 Sep 2020 17:23:47

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:22:56', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3bb0af75-32f1-4500-b502-c2ca6884815f' User entered '97.0'	System	11 Sep 2020 17:23:47
	System	11 Sep 2020 17:23:47

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:22:44', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3bb0af75-32f1-4500-b502-c2ca6884815f'	System	11 Sep 2020 17:23:47
User entered 'No (N)'	System	11 Sep 2020 17:23:47

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:23:03', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '3bb0af75-32f1-4500-b502-c2ca6884815f'	System	11 Sep 2020 17:23:47
User entered '11 Sep 2020 13:23'	System	11 Sep 2020 17:23:47

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 13:22'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 15:52'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:06', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a48ef82f-0fe8-4fbf-a5f1-75451356ba28'	System	11 Sep 2020 21:34:18
User entered 'Yes (Y)'	System	11 Sep 2020 21:34:18

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:22', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a48ef82f-0fe8-4fbf-a5f1-75451356ba28'	System	11 Sep 2020 21:34:18
User entered '98.2'	System	11 Sep 2020 21:34:18

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:30', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a48ef82f-0fe8-4fbf-a5f1-75451356ba28'	System	11 Sep 2020 21:34:18
User entered 'No (N)'	System	11 Sep 2020 21:34:18

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:36', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a48ef82f-0fe8-4fbf-a5f1-75451356ba28'	System	11 Sep 2020 21:34:18
User entered '11 Sep 2020 17:33'	System	11 Sep 2020 21:34:18

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 16:47'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 2'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 3'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 4'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 5'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 6'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 7'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:48:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e86a86d2-836b-4e78-a889-d1a9e50acfda'	System	18 Sep 2020 00:49:08
User entered 'Yes (Y)'	System	18 Sep 2020 00:49:08

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:48:52', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e86a86d2-836b-4e78-a889-d1a9e50acfd'	System	18 Sep 2020 00:49:08
User entered '96.2'	System	18 Sep 2020 00:49:08

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:00', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e86a86d2-836b-4e78-a889-d1a9e50acfda'	System	18 Sep 2020 00:49:08
User entered 'No (N)'	System	18 Sep 2020 00:49:08

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:06', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e86a86d2-836b-4e78-a889-d1a9e50acfd'	System	18 Sep 2020 00:49:08
User entered '17 Sep 2020 20:49'	System	18 Sep 2020 00:49:08

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:23:39', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'eb6b56cc-da8e-459f-9e5a-843667ddaa36'	System	11 Sep 2020 17:25:12
User entered 'None (1)'	System	11 Sep 2020 17:25:12

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:23:44', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'eb6b56cc-da8e-459f-9e5a-843667ddaa36'	System	11 Sep 2020 17:25:12
User entered 'No (N)'	System	11 Sep 2020 17:25:12

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:23:49', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'eb6b56cc-da8e-459f-9e5a-843667ddaa36'	System	11 Sep 2020 17:25:12
User entered 'No (N)'	System	11 Sep 2020 17:25:12

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:08', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'eb6b56cc-da8e-459f-9e5a-843667ddaa36'	System	11 Sep 2020 17:25:12
User entered 'None (1)'	System	11 Sep 2020 17:25:12

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:30', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'eb6b56cc-da8e-459f-9e5a-843667ddaa36'	System	11 Sep 2020 17:25:12
User entered '11 Sep 2020 13:24'	System	11 Sep 2020 17:25:12

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 13:22'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 15:52'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:50', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'ac533a20-4e32-4c5c-8122-e30c0ba04b53'	System	11 Sep 2020 21:34:56
User entered 'None (1)'	System	11 Sep 2020 21:34:56

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:33:58', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'ac533a20-4e32-4c5c-8122-e30c0ba04b53'	System	11 Sep 2020 21:34:56
User entered 'No (N)'	System	11 Sep 2020 21:34:56

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:04', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'ac533a20-4e32-4c5c-8122-e30c0ba04b53'	System	11 Sep 2020 21:34:56
User entered 'No (N)'	System	11 Sep 2020 21:34:56

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'ac533a20-4e32-4c5c-8122-e30c0ba04b53'	System	11 Sep 2020 21:34:56
User entered 'None (1)'	System	11 Sep 2020 21:34:56

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:15', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'ac533a20-4e32-4c5c-8122-e30c0ba04b53'	System	11 Sep 2020 21:34:56
User entered '11 Sep 2020 17:34'	System	11 Sep 2020 21:34:56

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 16:47'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 2'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 3'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 4'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 5'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 6'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 7'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:16', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4584ea0c-8663-499e-8c76-e515edfb87f9'	System	18 Sep 2020 00:49:43
User entered 'None (1)'	System	18 Sep 2020 00:49:43

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:21', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4584ea0c-8663-499e-8c76-e515edfb87f9'	System	18 Sep 2020 00:49:43
User entered 'No (N)'	System	18 Sep 2020 00:49:43

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:27', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4584ea0c-8663-499e-8c76-e515edfb87f9'	System	18 Sep 2020 00:49:43
User entered 'No (N)'	System	18 Sep 2020 00:49:43

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:34', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4584ea0c-8663-499e-8c76-e515edfb87f9'	System	18 Sep 2020 00:49:43
User entered 'None (1)'	System	18 Sep 2020 00:49:43

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:39', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '4584ea0c-8663-499e-8c76-e515edfb87f9'	System	18 Sep 2020 00:49:43
User entered '17 Sep 2020 20:49'	System	18 Sep 2020 00:49:43

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:47', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:24:58', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:25:04', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:25:32', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'None (0)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:25:50', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered 'No (N)'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T13:25:54', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '7fae660b-4081-446f-9293-e638bf18fb57'	System	11 Sep 2020 17:26:45
User entered '11 Sep 2020 13:25'	System	11 Sep 2020 17:26:45

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 13:22'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 15:52'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:26', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:33', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:41', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:34:59', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'None (0)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:35:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b'	System	11 Sep 2020 21:36:04
User entered 'No (N)'	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a2ee67b20f976794)', Time: '2020-09-11T17:35:23', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '8464a0ff-1ec3-4516-9b1a-e04f73aea01b' User entered '11 Sep 2020 17:35'	System	11 Sep 2020 21:36:04
	System	11 Sep 2020 21:36:04

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '11 Sep 2020 16:47'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 2'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 3'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 4'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 5'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 6'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
Data entry locked.	System	11 Sep 2020 17:14:39
User entered 'Day 7'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:47', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:49:59', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:50:04', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:50:11', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:50:17', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'None (0)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

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 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:50:25', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89'	System	18 Sep 2020 00:50:33
User entered 'No (N)'	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (12f92a9110b30713)', Time: '2020-09-17T20:50:28', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'f6876998-297f-4f96-8106-d3d05d85ed89' User entered '17 Sep 2020 20:50'	System	18 Sep 2020 00:50:33
	System	18 Sep 2020 00:50:33

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:14:39

US3172119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:30:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:37:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:14:39

US3172119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Sep 2020 20:08:27

US3172119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '19 Sep 2020'	Jessie Downs (b) (4) (b) (4)	21 Sep 2020 20:08:27

US3172119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	21 Sep 2020 20:08:27

US3172119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Sep 2020 20:08:27

US3172119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Sep 2020 20:08:31

US3172119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	21 Sep 2020 20:08:31

US3172119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:24:14

US3172119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:24:14

US3172119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:24:14

US3172119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:24:14

US3172119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:24:20

US3172119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	05 Oct 2020 19:24:20

US3172119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:25:58

US3172119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '02 Oct 2020'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:25:58

US3172119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:25:58

US3172119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:25:58

US3172119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:36
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 18:49:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 19:26:03

US3172119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	09 Oct 2020 20:29:36
User entered empty.	System	08 Oct 2020 18:49:30
User entered '1'	System	05 Oct 2020 19:26:03

US3172119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:52

US3172119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '09 Oct 2020'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:52

US3172119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:52

US3172119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'VISIT3'	System	09 Oct 2020 20:29:52

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '09 Oct 2020'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '10:52'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '09 Oct 2020 10:52'	System	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '80'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'bpm'	System	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'breaths/min'	System	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '91'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '65'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered 'mmHg'	System	09 Oct 2020 20:30:59

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55

US3172119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55

US3172119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:57

US3172119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:29:57

US3172119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:16

US3172119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '09 Oct 2020'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:16

US3172119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '11:10'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:16

US3172119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '09 Oct 2020 11:10'	System	09 Oct 2020 20:30:16

US3172119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:04
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	09 Oct 2020 20:30:19

US3172119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	09 Nov 2020 20:03:04
User entered empty.	System	09 Oct 2020 20:30:19

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 64'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 71'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 78'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 92'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered 'Day 99'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 20:20:48

US3172119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:43:04
Data entry locked.	System	14 Aug 2020 20:20:48
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 20:20:48

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-01-20T12:48:45', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'b37fff22-ef7c-4ec4-8ed5-90c4b9fa52d6'	System	20 Jan 2021 17:49:29
User entered 'No (N)'	System	20 Jan 2021 17:49:29

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-01-20T12:48:51', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'b37fff22-ef7c-4ec4-8ed5-90c4b9fa52d6'	System	20 Jan 2021 17:49:29
User entered 'No (N)'	System	20 Jan 2021 17:49:29

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-01-20T12:49:25', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'b37fff22-ef7c-4ec4-8ed5-90c4b9fa52d6'	System	20 Jan 2021 17:49:29
User entered '20 Jan 2021 12:49:25'	System	20 Jan 2021 17:49:29

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-02-14T18:06:46', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '24e5e9ff-5c11-4731-a296-33b9fa0dd107'	System	14 Feb 2021 23:10:54
User entered 'No (N)'	System	14 Feb 2021 23:10:54

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-02-14T18:06:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '24e5e9ff-5c11-4731-a296-33b9fa0dd107'	System	14 Feb 2021 23:10:54
User entered 'No (N)'	System	14 Feb 2021 23:10:54

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-02-14T18:07:01', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '24e5e9ff-5c11-4731-a296-33b9fa0dd107'	System	14 Feb 2021 23:10:54
User entered '14 Feb 2021 18:07:01'	System	14 Feb 2021 23:10:54

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-02-23T17:58:07', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '32c790e3-3080-4c33-8199-59480b64437c'	System	23 Feb 2021 22:58:27
User entered 'No (N)'	System	23 Feb 2021 22:58:27

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-02-23T17:58:12', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '32c790e3-3080-4c33-8199-59480b64437c'	System	23 Feb 2021 22:58:27
User entered 'No (N)'	System	23 Feb 2021 22:58:27

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-02-23T17:58:22', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '32c790e3-3080-4c33-8199-59480b64437c'	System	23 Feb 2021 22:58:27
User entered '23 Feb 2021 17:58:22'	System	23 Feb 2021 22:58:27

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-03-04T18:22:27', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'dc49b0a1-7ac0-4d24-8fa7-03dceec0333'	System	04 Mar 2021 23:26:50
User entered 'No (N)'	System	04 Mar 2021 23:26:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-03-04T18:22:33', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'dc49b0a1-7ac0-4d24-8fa7-03dceec0333'	System	04 Mar 2021 23:26:50
User entered 'No (N)'	System	04 Mar 2021 23:26:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-04T18:22:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'dc49b0a1-7ac0-4d24-8fa7-03dceec0333'	System	04 Mar 2021 23:26:50
User entered '04 Mar 2021 18:22:40'	System	04 Mar 2021 23:26:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-03-09T20:35:53', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '72dcff9f-7945-42e0-a73a-6b5ff878f69d'	System	10 Mar 2021 01:36:12
User entered 'No (N)'	System	10 Mar 2021 01:36:12

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-03-09T20:35:58', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '72dcff9f-7945-42e0-a73a-6b5ff878f69d'	System	10 Mar 2021 01:36:12
User entered 'No (N)'	System	10 Mar 2021 01:36:12

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-09T20:36:08', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '72dcff9f-7945-42e0-a73a-6b5ff878f69d'	System	10 Mar 2021 01:36:12
User entered '09 Mar 2021 20:36:08'	System	10 Mar 2021 01:36:12

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-03-15T10:16:55', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e9afa14f-aad5-472c-943f-d1a62ff6eb0a'	System	15 Mar 2021 14:17:10
User entered 'No (N)'	System	15 Mar 2021 14:17:10

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-03-15T10:17:00', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e9afa14f-aad5-472c-943f-d1a62ff6eb0a'	System	15 Mar 2021 14:17:10
User entered 'No (N)'	System	15 Mar 2021 14:17:10

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-15T10:17:06', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'e9afa14f-aad5-472c-943f-d1a62ff6eb0a'	System	15 Mar 2021 14:17:10
User entered '15 Mar 2021 10:17:06'	System	15 Mar 2021 14:17:10

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-03-21T09:09:03', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'aaf68766-0121-4807-8341-86ebccfa1ed0'	System	21 Mar 2021 13:09:20
User entered 'No (N)'	System	21 Mar 2021 13:09:20

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-03-21T09:09:09', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'aaf68766-0121-4807-8341-86ebccfa1ed0'	System	21 Mar 2021 13:09:20
User entered 'No (N)'	System	21 Mar 2021 13:09:20

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-21T09:09:15', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'aaf68766-0121-4807-8341-86ebccfa1ed0'	System	21 Mar 2021 13:09:20
User entered '21 Mar 2021 09:09:15'	System	21 Mar 2021 13:09:20

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-04-04T09:44:31', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '57d93d22-f79f-4550-b5d3-728637393bcd'	System	04 Apr 2021 13:44:41
User entered 'No (N)'	System	04 Apr 2021 13:44:41

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-04-04T09:44:36', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '57d93d22-f79f-4550-b5d3-728637393bcd'	System	04 Apr 2021 13:44:41
User entered 'No (N)'	System	04 Apr 2021 13:44:41

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-04-04T09:44:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '57d93d22-f79f-4550-b5d3-728637393bcd'	System	04 Apr 2021 13:44:41
User entered '04 Apr 2021 09:44:40'	System	04 Apr 2021 13:44:41

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-04-20T15:09:32', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bb482ecf-1ee4-4ee7-a35b-faecc35fabf7'	System	20 Apr 2021 19:09:50
User entered 'No (N)'	System	20 Apr 2021 19:09:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-04-20T15:09:37', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bb482ecf-1ee4-4ee7-a35b-faecc35fabf7'	System	20 Apr 2021 19:09:50
User entered 'No (N)'	System	20 Apr 2021 19:09:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-04-20T15:09:43', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'bb482ecf-1ee4-4ee7-a35b-faecc35fabf7'	System	20 Apr 2021 19:09:50
User entered '20 Apr 2021 15:09:43'	System	20 Apr 2021 19:09:50

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[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 (865bd898754e5330)', Time: '2021-04-28T14:44:48', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a7ae9993-f12e-43df-b9e2-7d986360fd2b'	System	28 Apr 2021 23:05:19
User entered 'No (N)'	System	28 Apr 2021 23:05:19

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

Have you been exposed to someone with 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 (865bd898754e5330)', Time: '2021-04-28T14:44:54', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a7ae9993-f12e-43df-b9e2-7d986360fd2b'	System	28 Apr 2021 23:05:19
User entered 'No (N)'	System	28 Apr 2021 23:05:19

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-04-28T14:44:58', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: 'a7ae9993-f12e-43df-b9e2-7d986360fd2b'	System	28 Apr 2021 23:05:19
User entered '28 Apr 2021 14:44:58'	System	28 Apr 2021 23:05:19

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:43:04

US3172119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:30:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:43:04
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:43:04

US3172119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:30:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-10T20:27:35', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0ab46301-0f5f-4733-9219-0c8ac5e59238'	System	11 Mar 2021 01:27:44
User entered 'No (N)'	System	11 Mar 2021 01:27:44

US3172119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:30:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:30:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (865bd898754e5330)', Time: '2021-03-10T20:27:40', User OID: 'PatientReportedOutcome (US3172119)', ODM File OID: '0ab46301-0f5f-4733-9219-0c8ac5e59238'	System	11 Mar 2021 01:27:44
User entered '10 Mar 2021 20:27:40'	System	11 Mar 2021 01:27:44

US3172119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:19

US3172119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '06 Nov 2020'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:19

US3172119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:19

US3172119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:19

US3172119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 20:03:42

US3172119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:32:55
User entered '1'	System	09 Nov 2020 20:03:42

US3172119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 19:51:25

US3172119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '10 Dec 2020'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 19:51:25

US3172119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 19:51:25

US3172119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 19:51:25

US3172119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Dec 2020 19:51:57

US3172119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:16
User entered '1'	System	10 Dec 2020 19:51:57

US3172119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Jan 2021 21:51:12

US3172119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '08 Jan 2021'	Jessie Downs (b) (4) (b) (4)	08 Jan 2021 21:51:12

US3172119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Jan 2021 21:51:12

US3172119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Jan 2021 21:51:12

US3172119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:49
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Jan 2021 21:51:03

US3172119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:04
User entered '1'	System	01 Feb 2021 22:21:49
User entered empty.	System	01 Feb 2021 22:21:32
User entered '1'	System	08 Jan 2021 21:51:03

US3172119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:25:49

US3172119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:25:49

US3172119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:25:49

US3172119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'missed open label'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:25:49

US3172119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:25:53

US3172119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:17:27
User entered '1'	System	26 Feb 2021 20:25:53

US3172119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:04

US3172119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Apr 2021 06:07:55
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed as entered.' (Site from System).	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:25
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 18:49:04
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:04

US3172119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:04

US3172119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 18:49:04

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '08:48'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:48'	System	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '83'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '13'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '91'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '62'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:50:20

US3172119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:32

US3172119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:32

US3172119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:39

US3172119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:39

US3172119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:39

US3172119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:49:39

US3172119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:49:43

US3172119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 18:49:43

US3172119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:58:08

US3172119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '09 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 14:58:08

US3172119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Apr 2021 14:58:08

US3172119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 14:58:08

US3172119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:58:13

US3172119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 14:58:13

US3172119

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:35

US3172119

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:35

US3172119

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:35

US3172119

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

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 15:47:35

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 22:18:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:49:14

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:35:07
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 22:18:28
' answered with 'Data updated ' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 22:18:03
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 21:01:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:49:14

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '1'	System	23 Jan 2021 15:47:54

US3172119

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

Form: Unblinding

Generated On: 09 Jun 2021 15:30:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '1'	System	23 Jan 2021 15:47:54

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered empty.	System	23 Jan 2021 15:49:21
DataPoint set to visible.	System	23 Jan 2021 15:47:54

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered empty.	System	23 Jan 2021 15:49:21
DataPoint set to visible.	System	23 Jan 2021 15:47:54

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '12:00'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '22 Jan 2021 12:00'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '82'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'bpm'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '16'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'breaths/min'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '129'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '79'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:30:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered empty.	System	23 Jan 2021 15:49:21
DataPoint set to visible.	System	23 Jan 2021 15:47:54

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '14:36'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '22 Jan 2021 14:36'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '73'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'bpm'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '16'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'breaths/min'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '136'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '76'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:21

US3172119

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	23 Jan 2021 15:49:21

US3172119

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:33

US3172119

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:33

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mRNA-1273'	System	23 Jan 2021 15:49:58
DataPoint set to visible.	System	23 Jan 2021 15:47:54

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '14:06'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '22 Jan 2021 14:06'	System	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'ONCE'	System	23 Jan 2021 15:49:58

US3172119

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

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 15:49:58

US3172119

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:29

US3172119

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:29

US3172119

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '13:25'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:29

US3172119

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '22 Jan 2021 13:25'	System	23 Jan 2021 15:50:29

US3172119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:42

US3172119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:42

US3172119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '13:26'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:42

US3172119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '22 Jan 2021 13:26'	System	23 Jan 2021 15:50:42

US3172119

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

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 15:50:46

US3172119

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

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '1'	System	23 Jan 2021 15:50:46

US3172119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:45

US3172119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:45

US3172119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:45

US3172119

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:45

US3172119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Feb 2021 22:21:57

US3172119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User entered '1'	System	01 Feb 2021 22:21:57

US3172119

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User entered '1'	System	01 Feb 2021 22:21:57
DataPoint set to visible.	System	01 Feb 2021 22:21:57

US3172119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:16

US3172119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '02 Mar 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:16

US3172119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:16

US3172119

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'OLD29'	System	02 Mar 2021 20:13:16

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '02 Mar 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '09:00'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '02 Mar 2021 09:00'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '98'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'bpm'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '18'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'breaths/min'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '133'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '69'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '02 Mar 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '12:20'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '02 Mar 2021 12:20'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '96'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'bpm'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '18'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'breaths/min'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '133'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '74'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:30:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mmHg'	System	02 Mar 2021 20:15:05

US3172119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:54

US3172119

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '02 Mar 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:54

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'mRNA-1273'	System	02 Mar 2021 20:13:39
DataPoint set to visible.	System	01 Feb 2021 22:21:57

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '02 Mar 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '11:50'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '02 Mar 2021 11:50'	System	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'ONCE'	System	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:30:08

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 20:13:39

US3172119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:13:43

US3172119

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:16
User entered '1'	System	02 Mar 2021 20:13:43

US3172119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:10:58
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 14:34:37

US3172119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:10:58
User entered '10 Mar 2021'	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 14:34:37

US3172119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:10:58
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 14:34:37

US3172119

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:30:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:10:58
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 14:34:37

US3172119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:44:32

US3172119

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:30:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:59:31
User entered 'I'	System	16 Mar 2021 19:44:32

US3172119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:50

US3172119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:50

US3172119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:50:50

US3172119

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:30:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:50:50

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '08:48'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 08:48'	System	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '83'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '13'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '91'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '62'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:30:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 18:51:22

US3172119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:27

US3172119

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:30:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:27

US3172119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:43

US3172119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:43

US3172119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '09:36'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:51:43

US3172119

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:30:08

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 09:36'	System	30 Mar 2021 18:51:43

US3172119

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:30:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 14:40:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:37
User entered 'USA-US118-2021-mRNA-1273-P301000009'	System	03 Mar 2021 15:15:32
User entered 'New'	(b) (4), (b) (6)	03 Mar 2021 15:15:32

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Rib fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:56:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:56:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Data point term sent to Coder	System	02 Mar 2021 20:22:34
User entered 'LEFT SIDE RIB CAGE MULTIPLE FRACTURE'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6) [Redacted]	10 Mar 2021 15:38:55
	Mark Kutner (b) (4) [Redacted] (b) (4)	09 Mar 2021 14:40:13
User entered empty.	Jessie Downs (b) (4) [Redacted] (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Mar 2021 20:27:07
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 Mar 2021 20:22:10
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:40:13
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Mar 2021 20:27:07
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	02 Mar 2021 20:27:07
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Mar 2021 20:27:07
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Mar 2021 20:22:10
User entered '0'	Jessie Downs (b) (4)	02 Mar 2021 20:22:10
	(b) (4)	

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	10 Mar 2021 15:41:23
	Mark Kutner (b) (4) [REDACTED] (b) (4)	09 Mar 2021 14:40:13
User entered '12 Feb 2021'	Jessie Downs (b) (4) [REDACTED] (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:04:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 19:04:42
User entered 'None (NONE)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 19:04:42
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 20:22:10
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

None

Audit	User	Time (GMT)
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:51:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:22:52
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:22:41
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)	10 Mar 2021 15:39:38
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'I'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:40:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:38:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:39:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	21 Mar 2021 07:09:50
	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 19:13:46

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME IN TODAY FOR 29 VISIT OPEN LABEL. SHE REPORTED SHE WENT TO THE ER ON 9FEB2021 IN VM HOSPITAL, WHERE SHE WAS ADMITTED AFTER FALL AND BROKE HER LEFT SIDE RIB CAGE MULTIPLE FRACTURE. NEW MEDS WAS ORDERED. MEDICAL RECORDS WILL BE REQUESTED TO UPDATE SAE AND FOLLOW UP. SUBJECT WAS ADMITTED AT UM HOSPITAL ON 09FEB2021 THROUGH 12FEB2021 AFTER MOTOR VEHICLE ACCIDENT WHILE SHE WAS RIDING A SCOOTER AND WAS WAS HIT BY THE BACK BY A CAR. C/O LEFT SIDE RIB PAIN: SHE WAS FOUND TO HAVE 4 POSTERIOR RIB FRACTURE AND WAS ADMITTED FOR PAIN CONTROL GIVEN EXCRUCIATING PAIN THAT WAS TREATMENT WITH BLOCK BY ANESTHESIA AND HER PAIN IMPROVED SUBSTANTIALLY. DUE TO PAIN EXACERBATION SHE WENT BACK TO THE HOSPITAL ON 19FEB2021 THROUGH 21FEB2021 FOR 2 DAYS. CT WAS PERFORMED WITHOUT CONTRAST SHOW. PROCEDURE DONE: CHEST TRAUMA MINOR. FRACTURE OF THE POSTERIOR LATERAL SEVERTH THROUGH TEN RIB. PARTIAL CALCIFIED NODULE SEE IN LEFT THYROID LOBE 0.6CM. EMPHYSEMATOUS LUNG CHANGES. SUBJECT WAS DISCHARGED HOME WITH ORAL MEDICATION. SUBJECT WAS DISCHARGED ON STABLE CONDITION AND PAIN WAS CONTROLLED. THIS ADMISSION WAS RELATED TO THE MAIN SAE DUE TO RIB PAIN EXACERBATION RELATED TO RIB TRAUMA. SUBJECT IS COMPLETELY RECOVERED AS PER SUBJECT REPORT BY PHONE CALLS. NO FOLLOW UP HAS BEEN DONE BY PCP DUE TO SUBJECT DOES NOT HAVE A PCP. LABORATORY RESULT WAS REVIEWED EXCEPT FOR HEPATITIS C . HCV,	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 19:13:46

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
RNA, QQN, PCR ABNORMAL/NCS. SUBJECT RECOVERED FROM THE EVENT AND CURRENTLY ASYMPTOMATIC.' reason for change: Data Entry Error		
User opened query 'Please add the event of "fall" ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:42:40
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:41:52
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Mar 2021 20:27:07
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Mar 2021 20:27:07
User entered 'SUBJECT CAME IN TODAY FOR 29 VISIT OPEN LABEL. SHE REPORTED SHE WENT TO THE ER ON 9FEB2021 IN VM HOSPITAL, WHERE SHE WAS ADMITTED AFTER FALL AND BROKE HER LEFT SIDE RIB CAGE MULTIPLE FRACTURE. NEW MEDS WAS ORDERED. MEDICAL RECORDS WILL BE REQUESTED TO UPDATE SAE AND FOLLOW UP.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:27:07
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Mar 2021 20:22:10
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:30:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 20:22:10

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[AEID](#)

Audit	User	Time (GMT)
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:05:16
User entered 'USA-US118-2021-mRNA-1273-P301000009' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 18:05:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:19
User entered 'USA-US118-2021-mRNA-1273-P301000011'	System	16 Mar 2021 17:14:12
User entered 'New'	(b) (4), (b) (6)	16 Mar 2021 17:14:12

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:11:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:11:26
Data point term sent to Coder	System	15 Mar 2021 20:28:48
User entered 'left pleural effusion secondary to left rib fracture'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Feb 2021'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Mar 2021 19:15:36
User entered 'No (N)'	Jessie Downs (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	18 Mar 2021 19:15:36
User entered '21 Feb 2021'	Jessie Downs (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Feb 2021'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: SAE's left rib fractures and left pleural effusion - 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). User entered '21 Feb 2021'	(b) (4), (b) (6)	23 Mar 2021 14:00:33
	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

None

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 02:43:53
User opened query 'SAE - left pleural effusion - 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)	23 Mar 2021 13:59:15
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'PV Query: SAE - left pleural effusion - PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User entered '0'	(b) (4), (b) (6) [REDACTED]	23 Mar 2021 13:58:46
	Jessie Downs (b) (4) [REDACTED]	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 19:15:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = EMPHYSEMATOUS LUNG CHANGES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 02:44:08
User opened query 'Per DM CLR: Narrative = PARTIAL CALCIFIED NODULE SEE IN LEFT THYROID LOBE 0.6CM. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 02:44:03
User opened query 'Per DM CLR: Narrative = TREATMENT WITH BLOCK BY ANESTHESIA. 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)	31 Mar 2021 02:43:58

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ON PHONE CALL TO FOLLOW UP, SUBJECT TODAY REPORTED THAT THEY WERE ADMITTED AT UM HOSPITAL ON 19FEB 2021 THROUGH 21FEB2021 FOR EXACERBATION OF PAIR RIB AND WAS DIAGNOSED WITH LEFT PLEURAL EFFUSION SECONDARY TO LEFT RIB FRACTURE. SUBJECT WAS DISCHARGED HOME WITH ORAL MEDICATION. PENDING MEDICAL RECORD RECORDS. SUBJECT WAS ADMITTED AT UM HOSPITAL ON 09FEB2021 THROUGH 12FEB2021 AFTER MOTOR VEHICLE ACCIDENT WHILE SHE WAS RIDING A SCOOTER AND WAS WAS HIT BY THE BACK BY A CAR. C/O LEFT SIDE RIB PAIN: SHE WAS FOUND TO HAVE 4 POSTERIOR RIB FRACTURE AND WAS ADMITTED FOR PAIN CONTROL GIVEN EXCRUCIATING PAIN THAT WAS TREATMENT WITH BLOCK BY ANESTHESIA AND HER PAIN IMPROVED SUBSTANTIALLY. DUE TO PAIN EXACERBATION SHE WENT BACK TO THE HOSPITAL ON 19FEB2021 THROUGH 21FEB2021 FOR 2 DAYS. CT WAS PERFORMED WITHOUT CONTRAST SHOW. PROCEDURE DONE: CHEST TRAUMA MINOR. FRACTURE OF THE POSTERIOR LATERAL SEVERTH THROUGH TEN RIB. PARTIAL CALCIFIED NODULE SEE IN LEFT THYROID LOBE 0.6CM. EMPHYSEMATOUS LUNG CHANGES. SUBJECT WAS DISCHARGED HOME WITH ORAL MEDICATION. SUBJECT WAS DISCHARGED ON STABLE CONDITION AND PAIN WAS CONTROLLED. THIS ADMISSION WAS RELATED TO THE MAIN SAE DUE TO RIB PAIN EXACERBATION RELATED TO RIB TRAUMA. SUBJECT IS COMPLETELY RECOVERED AS PER SUBJECT REPORT BY PHONE CALLS. NO FOLLOW UP HAS BEEN DONE BY PCP DUE TO SUBJECT DOES NOT HAVE A PCP. LABORATORY RESULT WAS	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 19:14:29

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
REVIEWED EXCEPT FOR HEPATITIS C . HCV, RNA, QQN, PCR ABNORMAL/NCS. SUBJECT RECOVERED FROM THE EVENT AND CURRENTLY ASYMPTOMATIC.' reason for change: Data Entry Error		
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 20:31:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 20:31:49
User entered 'on phone call to follow up, subject today reported that they were admitted at UM hospital on 19FEB 2021 through 21FEB2021 for exacerbation of pair rib and was diagnosed with left pleural effusion secondary to left rib fracture. subject was discharged home with oral medication. pending medical record records' reason for change: Data Entry Error	Jessie Downs (b) (4)	15 Mar 2021 20:31:49
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 20:28:04
User entered empty.	Jessie Downs (b) (4)	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:30:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Mar 2021 20:28:04

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymph node calcification, LLT: Lymph node calcification - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 19:52:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 19:52:19
Data point term sent to Coder	System	03 May 2021 18:53:43
User entered 'left thyroid node partially calcified'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

None

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 18:52:48

US3172119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:30:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 18:52:48

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:30:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:54:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:04:49

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:08:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:08:26
Data point term sent to Coder	System	18 Aug 2020 12:07:37
Data point term sent to Coder	System	18 Aug 2020 12:06:35
User entered 'MULTIVITAMIN'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 12:07:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 12:07:13
User entered 'PROPHYLAXIS' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:07:13
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 12:05:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '1'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'tablet (TABLET)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:31:19
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:37:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 12:05:42
User entered 'UN UNK 2015'	Mariete Rendon (b) (4)	18 Aug 2020 12:05:42
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 12:05:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:44:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:44:40
User closed query 'Per MM: Please include the generic ingredient(s) if known' (Site from DM). Data point term sent to Coder	(b) (4), (b) (6) System	11 Sep 2020 06:17:02
Query 'Per MM: Please include the generic ingredient(s) if known' answered with 'Data entered' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:40:11 10 Sep 2020 18:39:55
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:39:44
User entered 'FIBER (METHYLCELLULOSE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 18:39:44
User opened query 'Per MM: Please include the generic ingredient(s) if known' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:12:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:53:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 18:53:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: POLYCARBOPHIL CALCIUM, PRODUCTSYNONYM: FIBER - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:07:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

2170 of 2576

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'FIBER'	Coder Import (b) (4) (b) (4) System Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:07:20 18 Aug 2020 12:06:35 18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'CONSTIPATION'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '0.52'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'g (g)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:31:19
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:37:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 12:06:18
User entered 'UN UNK 2015'	Mariete Rendon (b) (4)	18 Aug 2020 12:06:18
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 12:06:18

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:08:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:08:27
Data point term sent to Coder	System	18 Aug 2020 12:07:36
User entered 'CALCIUM'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 15:31:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 12:06:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 12:06:59
User entered 'PROPHYLAXIS' reason for change: Data Entry Error	Mariete Rendon (b) (4)	18 Aug 2020 12:06:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 12:06:39
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 12:06:39
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '600'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:37:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 12:06:39
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 12:06:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:03:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:03:42
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:46:29 16 Mar 2021 19:46:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 11:04:57
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 11:04:57
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
Data point term sent to Coder User entered 'KETORALAC'	System Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:17:25 02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:04:11
Query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Dated updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:46:36
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:46:26
User entered 'LEFT RIB PAIN' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:46:26
User opened query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:56:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'PAIN'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '15'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'MG/ML'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per CDM RQ: Response noted. However, there is an available option for the "Frequency – once daily" in the drop-down list provided in the eCRF, please review, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:58:46
Query 'Per CDM RQ: Response noted. However, there is an available option for the "Frequency – once daily" in the drop-down list provided in the eCRF, please review, and update accordingly.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 20:52:36
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 20:52:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 20:52:13
User opened query 'Per CDM RQ: Response noted. However, there is an available option for the "Frequency – once daily" in the drop-down list provided in the eCRF, please review, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:40:06
User closed query 'Per CDM: Per your response of "once per day" please consider amending frequency to once daily which is a selection in the drop down menu.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:40:06
Query 'Per CDM: Per your response of "once per day" please consider amending frequency to once daily which is a selection in the drop down menu.' answered with 'medication was taken once daily on 09FEB2021 through 11FEB2021.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:48:48
User opened query 'Per CDM: Per your response of "once per day" please consider amending frequency to once daily which is a selection in the drop down menu.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 20:13:09
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 20:11:39

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'ONE DOSE PER DAY' (Site from System).	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:17:28
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	02 Mar 2021 20:16:35
User entered 'once (ONCE)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:51:21
	(b) (4)	
User entered '11 Feb 2021'	Jessie Downs (b) (4)	02 Mar 2021 20:16:35
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User entered '1'	System	23 Mar 2021 20:52:13
User entered empty.	System	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User entered '1'	System	23 Mar 2021 20:52:13
User entered empty.	System	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:41
User entered '804 (804)'	System	23 Mar 2021 20:52:13
User entered empty.	System	02 Mar 2021 20:16:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:09:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:09:39
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:47:33 16 Mar 2021 19:47:17
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 20:19:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 20:19:46
Data point term sent to Coder User entered 'OXYCODONE'	System Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:27 02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:05:20
Query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:47:25
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:47:17
User entered 'left rib PAIN' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 19:47:17
User opened query 'Per DM CLR: Please update the indication to reflect the location (bilateral, left, right) and/or type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:57:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'PAIN'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '10'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'PRN / EVERY 6 HOURS'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '12 Feb 2021'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:51:21
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 20:18:24

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:48:54
Data point term sent to Coder	System	18 Mar 2021 18:22:08
User entered 'diclofenac'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'left rib pain'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '50'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '12 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	18 Mar 2021 18:21:42
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '19 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User entered '3'	System	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User entered '1'	System	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:44
User entered '804 (804)'	System	18 Mar 2021 18:21:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:24:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:24:49
Data point term sent to Coder	System	18 Mar 2021 18:24:09
User entered 'alendronate'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:16
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:06:35
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:39:25
User entered 'osteoporosis'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '70'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'every week (QS)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	18 Mar 2021 18:23:10

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:25:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:25:41
Data point term sent to Coder	System	18 Mar 2021 18:25:10
User entered 'alprazolam'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:21
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:06:45
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:39:53
User entered 'anxiety'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '2'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:24:13

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:08:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 14:08:52
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:50 13 Apr 2021 14:07:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:25:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:25:40
Data point term sent to Coder User entered 'Symbicort'	System Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:11 18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:26
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:15
User entered 'Chronic obstructive pulmonary disease - COPD' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:12
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:40:15
User entered 'copd'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '80/4.5'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
	(b) (4)	
Query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:40:23
User opened query 'Per DM CLR: Please review and verify if the UNIT can be more appropriately recorded as UG as it is one of the pre-listed options. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:40:21
User entered 'ug (ug)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Mar 2021 15:41:57
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	18 Mar 2021 18:25:07
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 17:23:01
Query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 15:42:20
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 15:41:57
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 12:26:41
User entered 'mcg'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:25:07

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:26:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:26:41
Data point term sent to Coder	System	18 Mar 2021 18:26:11
User entered 'buspirone'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:32
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:21
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:41:00
User entered 'anxiety'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '10'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:25:42

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: BREXPIPRAZOLE, PRODUCTSYNONYM: REXULTI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:27:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:27:50
Data point term sent to Coder	System	18 Mar 2021 18:27:12
User entered 'rexulti'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:38
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:26
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:41:10
User entered 'major depression'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '2'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'bedtime'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:26:41

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:28:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:28:58
Data point term sent to Coder	System	18 Mar 2021 18:28:14
User entered 'trazodone'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:45
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:07:31
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:41:55
User entered 'depression'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '150'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'bedtime'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:27:19

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:32:11
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:08:51 13 Apr 2021 14:08:02
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:30:41
Data point term sent to Coder User entered 'pantoprazole'	System Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:29:21 18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' '(Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:52
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:08:17
User entered 'Gastroesophageal reflux disease - GERD' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:08:02
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' '(Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:42:07
User entered 'gerd'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '40'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '12 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:06:11
	(b) (4)	
User entered '14 Feb 2021'	Jessie Downs (b) (4)	18 Mar 2021 18:28:35
	(b) (4)	

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User entered '2'	System	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User entered '1'	System	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:31
User entered '804 (804)'	System	18 Mar 2021 18:28:35

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:30:41
Data point term sent to Coder	System	18 Mar 2021 18:30:23
User entered 'venlafaxine'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:24:58
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Medical history was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:08:34
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:42:37
User entered 'anti-depressant'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '150'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'un UNK 2002'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:30:06

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANESTHETICS FOR TOPICAL USE, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:06:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:06:44
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:07 13 Apr 2021 14:38:06
User entered 'LIDOCAINE 700mg, 50mg x gram adhesive' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:55:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:55:07
Data point term sent to Coder User entered 'lidocaine'	System Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:24 18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
Un-reviewed for Data Management.	(b) (4), (b) (6)	02 Apr 2021 07:42:47
Reviewed for Data Management.	(b) (4), (b) (6)	02 Apr 2021 07:42:44
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'left side rib pain'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Note, 5 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:25:05
Query 'Per DM CLR: Note, 5 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:47
User entered '750' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:36
User opened query 'Per DM CLR: Note, 5 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:42:52
User entered '5'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:36
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:38:36
User entered '%'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Topical (TOPICAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '19 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:31:00

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:02:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:02:53
Data point term sent to Coder	System	18 Mar 2021 18:46:42
User entered 'voltanen'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'left side rib pain'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User closed query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:25:10
Query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:39:24
User entered '1.16' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 14:39:15
User opened query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:43:03
User entered '1'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '%'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'four times daily (QID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Topical (TOPICAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '19 Feb 2019'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:46:32

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:49:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:49:50
Data point term sent to Coder	System	18 Mar 2021 18:48:09
User entered 'acetaminophen'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'left side rib pain'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '325'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'four times daily (QID)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '19 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:30:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 18:47:46

US3172119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:30:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 15:31:19
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 13:55:11

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '03/Mar/2021 10:16'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '1'	(b) (4), (b) (6)	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '04/Mar/2021 08:51'	System	04 Mar 2021 13:51:19

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered '1'	(b) (4), (b) (6)	04 Mar 2021 13:51:19

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered '16/Mar/2021 10:09'	System	16 Mar 2021 17:09:29

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered '1'	(b) (4), (b) (6)	16 Mar 2021 17:09:29

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '16/Mar/2021 18:07'	System	16 Mar 2021 18:08:02

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '1'	(b) (4), (b) (6)	16 Mar 2021 18:08:02

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'USA-US118-2021-MRNA-1273-P301000009'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Yes (Y)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'No (N)'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Mark'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'Kutner'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:15:54
User entered 'FL'	System	03 Mar 2021 15:15:32

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 18:07:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:40:13
User entered 'US'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Mar 2021 15:05:10
User entered '4'	System	16 Mar 2021 18:08:02
User entered '3'	System	16 Mar 2021 17:09:29
User entered '2'	System	04 Mar 2021 13:51:19
User entered '1'	System	03 Mar 2021 15:16:01

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '19/Mar/2021 08:05'	System	19 Mar 2021 15:05:10

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:06:11
User entered '1'	(b) (4), (b) (6)	19 Mar 2021 15:05:10

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'USA-US118-2021-MRNA-1273-P301000011'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Yes (Y)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Yes (Y)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Mark'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Kutner'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'FL'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered 'US'	System	16 Mar 2021 17:15:08

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 17:15:08

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'USA-US118-2021-MRNA-1273-P301000011'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Yes (Y)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Yes (Y)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'No (N)'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Mark'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'Kutner'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 17:14:45
User entered 'FL'	System	16 Mar 2021 17:14:12

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered 'US'	System	16 Mar 2021 17:15:08

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:30:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 17:15:08

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered '16/Mar/2021 10:15'	System	16 Mar 2021 17:15:08

US3172119

Folder: SAE USA-US118-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:30:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Mar 2021 17:57:06
User entered '1'	(b) (4), (b) (6)	16 Mar 2021 17:15:08