

US3222059 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: (b) (6)

Generated On: 11 Jun 2021 14:58:14

All time stamps listed in this document are displayed in GMT

US3222059

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

[Participant ID](#)

US3222059

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

US3222059

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Date of Birth (MMM yyyy)	(b) (6) 1936
Age	84
Age Units	YEARS
Age (Derived)	84
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

US3222059

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Date of Informed Consent (<i>dd MMM yyyy</i>)	8 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3222059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3222059

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Were any significant conditions reported?

Yes ☒

No ☐

US3222059

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	01 JAN 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	ALLERGIES- SEASONAL
Start date (dd MMM yyyy)	01 JAN 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	BACK PROBLEMS
Start date (dd MMM yyyy)	01 JAN 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	BRONCHITIS
Start date (dd MMM yyyy)	01 JAN 2004
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)	01 JAN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3222059

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	CATARACT SURGERY - BILATERAL
Start date (dd MMM yyyy)	01 JAN 1998
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)	01 JAN 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3222059

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	CHICKEN POX- CHILDHOOD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	GERD
Start date (dd MMM yyyy)	01 JAN 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	01 JAN 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	01 JAN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	KNEE REPLACEMENT-LEFT
Start date (dd MMM yyyy)	01 JAN 2013
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)	01 JAN 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3222059

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	MEASLES-CHILDHOOD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	MENINGITIS
Start date (dd MMM yyyy)	01 JAN 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	MUMPS-CHILDHOOD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	NON-SMOKER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	OSTEOARTHRITIS - KNEES BILATERAL
Start date (dd MMM yyyy)	01 JAN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	01 JAN 1967
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	OSTEOARTHRITIS - HANDS BILATERAL
Start date (dd MMM yyyy)	01 JAN 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)	

US3222059

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	RUBELLA-CHILDHOOD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	SINUSITIS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222059

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	TINEA VERSICOLOR - UPPER BACK
Start date (dd MMM yyyy)	01 JAN 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Condition	ALLERGIES, ENVIRONMENTAL
Start date (dd MMM yyyy)	01 JAN 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

US3222059

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:45 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 16:45
Height (<i>xxx.x</i>)	160.0 cm
Weight (<i>xxx.x</i>)	65.5 kg
BMI (<i>xxx.x</i>)	25.58594 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222059

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

US3222059

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*) 08 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*) 01 JAN 1967

Date of last menstruation unknown False

US3222059

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3222059

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

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

What was the participant's randomization number? 185348

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 ☒

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Height	ND - Not Done
Weight	ND - Not Done

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 16:45
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	17:50 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 17:50
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 8 AUG 2020

What was the treatment time? (00:00-23:59) 17:20 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 17:20

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

US3222059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 AUG 2020

Collection time (00:00-23:59)

17:00 (24 HR)

Collection date and time (derived)

08 AUG 2020 17:00

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:05	08 AUG 2020 17:05
Nasopharyngeal Swab 2	No		

US3222059

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:05

PC Open Date & Time

08 AUG 2020 17:40

PC Close Date & Time

08 AUG 2020 20:10

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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

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

08 AUG 2020 21:05

PC Close Date & Time

09 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 11:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:06

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

12 AUG 2020 18:23

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 18:13

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 19:45

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:06

PC Open Date & Time

08 AUG 2020 17:40

PC Close Date & Time

08 AUG 2020 20:10

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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 ☐

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

08 AUG 2020 21:05

PC Close Date & Time

09 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:25

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 18:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:24

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 18:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 19:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 18:07
PC Open Date & Time	08 AUG 2020 17:40
PC Close Date & Time	08 AUG 2020 20:10

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 AUG 2020 21:05

PC Close Date & Time

09 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

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 ☒

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 11:26
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 2428

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 18:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 2428

EAB) (1725)

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:05
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

69 of 2428

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 18:24
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

71 of 2428

EAB) (1725)

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 18:15
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

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 ☒

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 19:46
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:06
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:45 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 13:45

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

US3222059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	13:21 (24 HR)
Collection date and time (derived)	14 SEP 2020 13:21

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:08:45

Generated On: 11 Jun 2021 14:58:14

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:27	14 SEP 2020 13:27
Nasopharyngeal Swab 2	No		

US3222059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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

98.0 °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

14 SEP 2020 14:17

PC Open Date & Time

14 SEP 2020 14:05

PC Close Date & Time

14 SEP 2020 16:35

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	14 SEP 2020 18:26
PC Open Date & Time	14 SEP 2020 17:30
PC Close Date & Time	15 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

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

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

17 SEP 2020 11:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:29

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 13:08

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 14:17

PC Open Date & Time

14 SEP 2020 14:05

PC Close Date & Time

14 SEP 2020 16:35

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:27

PC Open Date & Time

14 SEP 2020 17:30

PC Close Date & Time

15 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 11:37

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:29

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 13:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 18:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 14:18
PC Open Date & Time	14 SEP 2020 14:05
PC Close Date & Time	14 SEP 2020 16:35

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 18:28
PC Open Date & Time	14 SEP 2020 17:30
PC Close Date & Time	15 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

109 of 2428

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2428

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 11:38
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

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 ☒

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

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 ☒

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:30
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

117 of 2428

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 13:09
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

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 ☒

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 18:56
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3222059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:09:07

Generated On: 11 Jun 2021 14:58:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

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.

US3222059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	12:33 (24 HR)
Collection date and time (derived)	13 OCT 2020 12:33

US3222059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:06

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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"/>

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 10:28:21

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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"/>

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 23:00:29

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 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	12 NOV 2020 18:25:48
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 11:31:25
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 16:08:16

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 23:35:56

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 10:38:42

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 11:25:14

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 10:47:19

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 10:15:23

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 16:51:49
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 18:04:36
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 11:18:24

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 11:37:14

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 11:21:32
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 09:55:35
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 FEB 2021 09:01:22
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 23:19:18

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 18:17:50

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 09:36:19

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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	30 MAR 2021 10:20:49
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 10:48:49

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 10:59:02

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

30 APR 2021 17:33:43

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	16 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	20 AUG 2021 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 397

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

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

No ☐
Yes ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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°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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 425

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐
Yes ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	25 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	29 OCT 2021 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	15 NOV 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	19 NOV 2021 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	27 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	31 DEC 2021 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	25 APR 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 APR 2022 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2022 00:01
Patient Cloud Close Date & Time	22 JUL 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	25 JUL 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 JUL 2022 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 726

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

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

No ☐

Yes ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	19 AUG 2022 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

Patient Cloud Open Date & Time	03 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	07 OCT 2022 23:59
---	-------------------

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3222059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:36:49

Generated On: 11 Jun 2021 14:58:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

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.

US3222059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	18 MAR 2021 13:40

US3222059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:36:49

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:36:49

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222059

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Jun 2021 14:58:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222059

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3222059

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:36:49

Generated On: 11 Jun 2021 14:58:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 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>)	19 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

US3222059

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Height	160.0 cm
Weight	65.5 kg
BMI (xxx.x)	25.58594

US3222059

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Height	160.0 cm
Weight	65.5 kg
BMI (xxx.x)	25.58594
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)	19 JAN 2021
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 15:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Height	160.0 cm
Weight	65.5 kg
BMI (xxx.x)	25.58594
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)	19 JAN 2021
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 15:55
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3222059

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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) 19 JAN 2021

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

Treatment Date and Time (derived) 19 JAN 2021 15:24

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

What was the frequency of the study treatment dosing? ONCE

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

US3222059

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	19 JAN 2021 14:25

US3222059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	14:28
Collection Date and Time (derived)	19 JAN 2021 14:28

US3222059

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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)	16 FEB 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 13:36
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	15:11 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 15:11
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3222059

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3222059

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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) 16 FEB 2021

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 14:40

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

US3222059

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222059

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222059

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:12:42

Generated On: 11 Jun 2021 14:58:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 17:12:43

Generated On: 11 Jun 2021 14:58:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222059

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:12:42

Generated On: 11 Jun 2021 14:58:14

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.

US3222059

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:12:42

Generated On: 11 Jun 2021 14:58:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	13:40 (24 HR)
Collection date and time (derived)	18 MAR 2021 13:40

US3222059

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

AEID	USA-US104-2020-MRNA-1273-P30 1000001
Adverse event	NEW ONSET-ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	5 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	363 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

I WAS CALLED BY THE
PATIENT TONIGHT 06/SEP/2020
SUBJECT WENT TO A
REGULARLY SCHEDULED
DOCTOR'S APPOINTMENT ON
03/SEP/2020, AND HER
PHYSICIAN LISTENED TO HER
BREATH SOUNDS AND THEN
APICAL AND SAID YOUR
HEART RATE IS TOO FAST AND
SENT HER TO THE EMERGENCY
ROOM. WHERE THEY
DIAGNOSED HER WITH NEW
ONSET OF A-FIB. SHE STAYED
FROM 03/SEP/2020 AND
DISCHARGED ON 05/SEP/2020. I
AM REQUESTING THE
DISCHARGE SUMMARY
DIAGNOSED WITH ATRIAL
FIBRILLATION WITH RVR, AND
ESSENTIAL HYPERTENSION.
SHE WAS EVALUATED BY A
CARDIOLOGIS WHO
PRESCRIBED HER ELIQUIS AND
PRESCRIBED HER
METOPROLOL WITH
INSTRUCTIONS NOT TO TAKE
WHEN HEART RATES IS LESS
THAN 58 OR BLOOD PRESSURE
IS LESS THAN 110 SYSTOLIC,
HEART RYTHM CONFIRMED BY
EKG PRIOR TO DISCHARGE.
PCR WAS COLLECT AND
NEGATIVE FOR COVID-19.
LABS: WBC HIGH

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

10.9X1083/MICROL 04/SEP/2020
RBC LOW 4.16X1086/MICROL
04/SEP/2020 GLUCOSE HIGH 109
M/DL 04/SEP/2020 TREATMENT:
CARDIOLOGIST TREATED
PATIENT WITH UNSPECIFIED
ANTIARRHYTHMICS AND
ELIQUIS FOR CLOT
PREVENTION. SHE WAS
CONFIRMED STABLE THE
FOLLOWING DAY FOR
DISCHARGE.

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

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

AEID	
Adverse event	ESSENTIAL HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

367 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DIAGNOSIS IS SECONDARY TO THE SAE.
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)	

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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

Yes ☒

No ☐

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

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication ACETAMENOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS - KNEES - B/L

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

370 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2000
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC RHINITIS

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)

372 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	01 JAN 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

Dose per administration 180

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)

374 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2009	
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"/>

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication	ELIQUIS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	A-FIB
Dose per administration	2.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

	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)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication A-FIB/ESSENTIAL HTN

Dose per administration 25

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)

378 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication DILTIAZAM

Prophylaxis Yes ☐
No ☒

Indication A-FIB

Dose per administration 180

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)

380 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Name of Medication PROTONIX

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

382 of 2428

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2010	
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"/>

US3222059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 15:08:43

Generated On: 11 Jun 2021 14:58:14

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3222059

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 14:58:14

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

US3222059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 14:58:14

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 ☐

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/SEP/2020 08:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/OCT/2020 09:53
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/NOV/2020 17:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	False

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 14:14
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	19/NOV/2020 15:44
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	25/NOV/2020 11:33
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/DEC/2020 10:44
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/DEC/2020 08:18
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

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 19 Feb 2021 15:08:44

Generated On: 11 Jun 2021 14:58:14

SAEID	USA-US104-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/DEC/2020 16:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3222059 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222059

Form: Participant Creation

Generated On: 11 Jun 2021 14:58:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'US3222059'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:00:27

US3222059

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:06:59

US3222059

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:00:28

US3222059

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:06:59

US3222059

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'SCRN'	System	08 Aug 2020 21:06:59

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered (b) (6) 1936'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:00:28

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '84'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'YEARS'	System	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '84'	System	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Female (F)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 14:58:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:52:44

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered '8 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Aug 2020'	System	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2020'	System	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:07:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 21:07:15
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 21:07:10
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	08 Aug 2020 21:07:10

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:16:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:00:28

US3222059

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 14:58:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'I'	System	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 14:58:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:53:12

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:01:18
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 14:58:24
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:55:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:59
Data point term sent to Coder	System	10 Aug 2020 19:55:30
User entered 'Allergic Rhinitis'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2001'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2001'	System	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2001'	System	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:54:52

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:01:43
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 14:58:37
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:55:46
User closed query "" Per MM: Please review and consider capturing ALLERGIES- SEASONAL (PT: SEASONAL ALLERGY) and ALLERGIES-ENVIRONMENTAL (PT: HYPERSENSITIVITY) separately. Update as appropriate." ' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 17:35:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 14:47:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 14:47:50
Data point term sent to Coder	System	06 Sep 2020 14:46:50
User closed query 'For coding purposes, please split ALLERGIES- SEASONAL & ENVIRONMENTAL into separate entries' (Site from System).	System	06 Sep 2020 14:46:21

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please split ALLERGIES- SEASONAL & ENVIRONMENTAL into separate entries' answered with 'UPDATED PER REQUEST' (Site from System).	Amber Vasquez (b) (4)	06 Sep 2020 14:46:21
Query "" Per MM: Please review and consider capturing ALLERGIES- SEASONAL (PT: SEASONAL ALLERGY) and ALLERGIES-ENVIRONMENTAL (PT: HYPERSENSITIVITY) separately. Update as appropriate." ' answered with 'UPDATED PER REQUEST' (Site from DM).	Amber Vasquez (b) (4)	06 Sep 2020 14:46:09
Coding entries removed.	Amber Vasquez (b) (4)	06 Sep 2020 14:45:55
User entered 'ALLERGIES- SEASONAL' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Sep 2020 14:45:55
User opened query 'For coding purposes, please split ALLERGIES- SEASONAL & ENVIRONMENTAL into separate entries' (Site from System).	Coder Import (b) (4)	04 Sep 2020 13:41:33
User opened query "" Per MM: Please review and consider capturing ALLERGIES- SEASONAL (PT: SEASONAL ALLERGY) and ALLERGIES-ENVIRONMENTAL (PT: HYPERSENSITIVITY) separately. Update as appropriate." ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 10:50:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:36:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 13:36:14
Data point term sent to Coder	System	14 Aug 2020 23:59:26
Datapoint queued for coding (5024686).	System	14 Aug 2020 23:59:12
User entered 'ALLERGIES- seasonal & environmental' reason for change: Data Entry Error	Crystal Paccione (b) (4)	10 Aug 2020 19:55:44
Data point term sent to Coder	System	10 Aug 2020 19:55:32
User entered 'Allergies'	Crystal Paccione (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2001'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2001'	System	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2001'	System	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:55:20

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: Please verify MH term and specify the type of BACK PROBLEMS to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:25:15
Query 'Per DM CLR: Please verify MH term and specify the type of BACK PROBLEMS to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' answered with 'PATIENT CANNOT SPECIFY AS THERE IS NO OFFICAL DX' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:46:57
User opened query 'Per DM CLR: Please verify MH term and specify the type of BACK PROBLEMS to reflect a medical condition or diagnosis as appropriate. Please reconcile with applicable eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:02:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue conditions NEC, PT: Back disorder, LLT: Back disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:04:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:04:19
Data point term sent to Coder	System	14 Aug 2020 18:02:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue conditions NEC, PT: Back disorder, LLT: Back disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:02:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:02:19
Query 'DM-Coding: please provide more information. Is this Back injury/Back pain/Back sprain/Back arthritis and etc. Please update this term in accordance with your answer.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	14 Aug 2020 18:02:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

452 of 2428

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: please provide more information. Is this Back injury/Back pain/Back sprain/Back arthritis and etc. Please update this term in accordance with your answer.' (Site from System). Data point term sent to Coder	Coder Import (b) (4)	13 Aug 2020 08:09:15
User entered 'Back problems'	System	10 Aug 2020 19:56:33
	Crystal Paccione (b) (4)	10 Aug 2020 19:56:05
	(b) (4)	

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2006'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2006'	System	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2006'	System	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:56:05

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:03:20
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'THIS CONDITION HAS ENDED AS NOTED BELOW. THERE WOULD NOT BE A TREATMENT. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:01:21
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:56:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:35
Data point term sent to Coder	System	10 Aug 2020 19:57:34
User entered 'Bronchitis'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2004'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2019'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2004'	System	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2004'	System	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2019'	System	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2019'	System	10 Aug 2020 19:56:43

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.	Coder Import (b) (4)	24 Oct 2020 20:47:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Oct 2020 20:47:30
User closed query 'Per DM CLR: Please specify the eye laterality in CATARACT SURGERY. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:02:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:03:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:03:34
Data point term sent to Coder	System	14 Oct 2020 15:02:19
Query 'Per DM CLR: Please specify the eye laterality in CATARACT SURGERY. Review and update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	14 Oct 2020 15:01:39
Coding entries removed.	Albert Garcia (b) (4)	14 Oct 2020 15:01:36
User entered 'CATARACT SURGERY - BILATERAL' reason for change: Data Entry Error	Albert Garcia (b) (4)	14 Oct 2020 15:01:36
User opened query 'Per DM CLR: Please specify the eye laterality in CATARACT SURGERY. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:02:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:54

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 19:57:36
User entered 'Cataract Surgery'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:30
	(b) (4)	

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1998'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1998'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1998'	System	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1998'	System	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1998'	System	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (5)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1998'	System	10 Aug 2020 19:57:30

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Varicella, LLT: Chickenpox - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 22:19:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 22:19:15
Data point term sent to Coder	System	10 Aug 2020 19:58:39
User entered 'Chicken Pox- Childhood'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (6)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:57:53

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:03:06
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:01:54
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:56:26
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:56
Data point term sent to Coder	System	10 Aug 2020 19:58:41
User entered 'GERD'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1992'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1992'	System	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1992'	System	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (7)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:58:22

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	10 Aug 2020 19:59:43
User entered 'Hiatal Hernia'	Crystal Paccione (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1992'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1992'	System	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1992'	System	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (9)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:59:15

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Response noted however no updates have been made to the Con Med eCRF for this condition? Please review and update accordingly. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:02:04
Query 'Per CDM: Response noted however no updates have been made to the Con Med eCRF for this condition? Please review and update accordingly. Thanks.' answered with 'Not treated, diet controlled.' (Site from DM).	douglas winter (b) (4) (b) (4)	30 Oct 2020 15:08:46
User opened query 'Per CDM: Response noted however no updates have been made to the Con Med eCRF for this condition? Please review and update accordingly. Thanks.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:10:27
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:10:27
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:02:06
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:56:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

514 of 2428

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 20:00:44
User entered 'Hypercholesterolemia'	Crystal Paccione (b) (4)	10 Aug 2020 19:59:48
	(b) (4)	

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2019'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2019'	System	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2019'	System	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (10)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 19:59:48

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:20:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 17:20:20
Data point term sent to Coder	System	10 Aug 2020 20:00:45
User entered 'Knee replacement-left'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2013'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2013'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2013'	System	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2013'	System	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2013'	System	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (11)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2013'	System	10 Aug 2020 20:00:20

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rubeola viral infections, PT: Measles, LLT: Measles - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:27:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:27:20
Data point term sent to Coder	System	10 Aug 2020 20:00:50
User entered 'MEASLES-Childhood' reason for change: Data Entry Error	Crystal Paccione (b) (4)	10 Aug 2020 20:00:49
Data point term sent to Coder	System	10 Aug 2020 20:00:48
User entered 'Measles'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (12)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:00:37

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Central nervous system and spinal infections, PT: Meningitis, LLT: Meningitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:59
Data point term sent to Coder	System	10 Aug 2020 20:01:53
User entered 'Meningitis'	Crystal Paccione (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1996'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1996'	System	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1996'	System	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (13)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:20

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Mumps viral infections, PT: Mumps, LLT: Mumps - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 07:24:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 07:24:27
Data point term sent to Coder	System	10 Aug 2020 20:01:57
User entered 'Mumps-Childhood'	Crystal Paccione (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (14)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:01:48

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Tobacco use, PT: Non-tobacco user, LLT: Non-smoker - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:52
Data point term sent to Coder	System	10 Aug 2020 20:02:58
User entered 'Non-Smoker'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (15)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:09

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:47
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:57:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:04:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:04:27
Data point term sent to Coder	System	14 Oct 2020 15:03:21
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:03:18
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:03:14
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:03:11
User entered 'OSTEOARTHRITIS - KNEES BILATERAL' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:03:11
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:57:41

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:04:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:51
Data point term sent to Coder	System	10 Aug 2020 20:02:59
User entered 'Osteoarthritis'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1990'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1990'	System	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1990'	System	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (16)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:02:47

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:46
Data point term sent to Coder	System	10 Aug 2020 20:04:00
User entered 'Post-menopausal'	Crystal Paccione (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1967'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 1967'	System	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '1967'	System	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (17)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:03:22

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:36:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:36:58
User closed query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	09 Nov 2020 11:58:24
' (Site from DM).		
Data point term sent to Coder	System	06 Nov 2020 17:47:48
Query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	Albert Garcia (b) (4)	06 Nov 2020 17:46:51
' answered with 'UPDATED' (Site from DM).	(b) (4)	
Coding entries removed.	Albert Garcia (b) (4)	06 Nov 2020 17:46:47
User entered 'OSTEOARTHRITIS - HANDS BILATERAL' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM CR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	Albert Garcia (b) (4)	06 Nov 2020 17:46:47
' (Site from DM).	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.'	(b) (4), (b) (6)	27 Oct 2020 13:40:41
' (Site from DM).		
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.'	(b) (4), (b) (6)	22 Oct 2020 15:05:01
' (Site from DM).		

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:04:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 06:49:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 06:49:22
Data point term sent to Coder	System	14 Oct 2020 15:17:46
Query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:17:42
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:17:37
User entered 'RHEUMATOID ARTHRITIS - HANDS BILATERAL' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:17:37
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'NOT CURRENTLY TREATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:17:25
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:04:44
User opened query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:04:38

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:27
Data point term sent to Coder	System	10 Aug 2020 20:05:01
User entered 'RHEUMATOID ARTHRITIS'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2000'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2000'	System	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2000'	System	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (18)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:10

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rubella viral infections, PT: Rubella, LLT: Rubella - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 08:48:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 08:48:19
Data point term sent to Coder	System	10 Aug 2020 20:05:02
User entered 'Rubella-Childhood'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (19)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:29

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 06:46:50
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:03:55
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:58:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:40
Data point term sent to Coder	System	10 Aug 2020 20:05:03
User entered 'Sinusitis'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'un UNK 2009' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	30 Oct 2020 15:03:47
User entered '01 Jan 2011'	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:04:53
	(b) (4)	

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2009'	System	30 Oct 2020 15:03:47
User entered 'Jan 2011'	System	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2009'	System	30 Oct 2020 15:03:47
User entered '2011'	System	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (20)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:04:53

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: Please specify the location of TINEA VERSICOLOR. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:56:13
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Tinea infections, PT: Tinea versicolour, LLT: Tinea versicolor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:53:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:53:18
Data point term sent to Coder	System	14 Oct 2020 15:05:26
Query 'Per DM CLR: Please specify the location of TINEA VERSICOLOR. Review and update Med History eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:05:07
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:05:04
User entered 'TINEA VERSICOLOR - UPPER BACK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:05:04
User opened query 'Per DM CLR: Please specify the location of TINEA VERSICOLOR. Review and update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:05:10
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Tinea infections, PT: Tinea versicolour, LLT: Tinea versicolor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:05
Data point term sent to Coder	System	10 Aug 2020 20:06:04
User entered 'Tinea Versicolor'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2010'	Crystal Paccione (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2010'	System	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2010'	System	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (21)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	10 Aug 2020 20:05:23

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:04:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:04:56
Data point term sent to Coder	System	06 Sep 2020 14:47:50
User entered 'ALLERGIES, ENVIRONMENTAL'	Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 2001'	Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Amber Vasquez (b) (4)	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'Jan 2001'	System	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '2001'	System	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Medical History (22)

Generated On: 11 Jun 2021 14:58:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered empty.	System	06 Sep 2020 14:46:59

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16:45'	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered '08 Aug 2020 16:45'	System	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '160.0' cm	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
DataPoint set to visible.	(b) (4) System	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '65.5' kg	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
DataPoint set to visible.	(b) (4) System	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
Amendment Manager: User entered '25.58594'	System	16 Sep 2020 23:49:09
User entered '25.6'	System	10 Aug 2020 20:06:51
DataPoint set to visible.	System	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'kg/m2'	System	10 Aug 2020 20:06:51
DataPoint set to visible.	System	08 Aug 2020 21:07:20

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:27:06
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:46:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:46:14
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:04:57
User entered '36.5' C	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	15 Sep 2020 20:46:14
User entered 'Oral (Oral)'	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:46:14
User entered '70'	Albert Garcia (b) (4)	15 Sep 2020 20:46:14
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
	(b) (4)	

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'bpm'	System	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:46:14
User entered '14'	Albert Garcia (b) (4)	15 Sep 2020 20:46:14
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
	(b) (4)	

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'breaths/min'	System	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:46:14
User entered '140'	Albert Garcia (b) (4)	15 Sep 2020 20:46:14
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
	(b) (4)	

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'mmHg'	System	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:46:14
User entered '70'	Albert Garcia (b) (4)	15 Sep 2020 20:46:14
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:06:51
	(b) (4)	

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User entered 'mmHg'	System	10 Aug 2020 20:06:51

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49

US3222059

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49

US3222059

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:07:07

US3222059

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	18 Sep 2020 18:58:26
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	18 Sep 2020 18:58:26
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:58:26
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:58:26
User entered '08 Aug 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:58:26
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	18 Sep 2020 18:58:22
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:58:22
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	18 Sep 2020 18:58:22
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:58:22
User entered '08 Mar 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:58:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 18:10:13
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	10 Aug 2020 20:07:13
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	10 Aug 2020 20:07:13

US3222059

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:13
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:13
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:13
User entered '08 Aug 2020' reason for change: Data Entry Error	Crystal Paccione (b) (4)	10 Aug 2020 20:07:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:07
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:07
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	10 Aug 2020 20:07:07
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	10 Aug 2020 20:07:07
User entered '08 Aug 2010'	Crystal Paccione (b) (4)	10 Aug 2020 20:07:07

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '01 Jan 1967' reason for change: Data Entry Error	(b) (4)	
	Amber Vasquez (b) (4)	01 Sep 2020 12:56:02
User entered empty.	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 20:07:33
	(b) (4)	

US3222059

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Jun 2021 14:58:14

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: Date of last menstruation unknown = Yes. However, 01 JAN 1967 is recorded as start date of POST MENOPAUSAL. Please review and reconcile as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:53:53
Query 'Per DM CLR: Date of last menstruation unknown = Yes. However, 01 JAN 1967 is recorded as start date of POST MENOPAUSAL. Please review and reconcile as appropriate. Otherwise, clarify in query response. ' answered with 'Updated' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 12:56:12
User entered '0' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 12:56:02
User opened query 'Per DM CLR: Date of last menstruation unknown = Yes. However, 01 JAN 1967 is recorded as start date of POST MENOPAUSAL. Please review and reconcile as appropriate. Otherwise, clarify in query response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 07:20:36
User entered '1'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:07:33

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

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)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 14:58:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:02:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Jennifer Dittman (b) (4)	08 Aug 2020 21:42:18

US3222059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:07:38

US3222059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 16:23:23
User entered '8 Aug 2020'	Jennifer Dittman (b) (4)	08 Aug 2020 21:07:38

US3222059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:07:38

US3222059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'VISIT1'	System	08 Aug 2020 21:07:38

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:05:24

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:09:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:09:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 21:05:24
User entered '185348' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:05:24

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 21:05:24

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

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)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:08:01

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

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)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:08:01

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:08:01

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:08:01

US3222059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 14:58:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:08:01

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:23:58
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:29
User entered '160.0' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:01
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:26
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:38
User entered '65.5' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:23:58
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:29
User entered '160.0' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:01
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:26
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:38
User entered '65.5' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16:45'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '08 Aug 2020 16:45'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.5' C	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '70'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'bpm'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'breaths/min'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '140'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '70'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:23:58
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:41
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:19
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:29
User entered '160.0' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:01
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:45:45
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:52:52
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:26
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:44:10
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:05:38
User entered '65.5' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 07:55:39
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol correct' (Site from System).	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:01
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).		10 Aug 2020 20:09:45
User entered '17:50'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '08 Aug 2020 17:50'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.2' C	Crystal Paccione (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '68'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'bpm'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'breaths/min'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '128'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '72'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	10 Aug 2020 20:09:45

US3222059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:13

US3222059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	Crystal Paccione (b) (4)	10 Aug 2020 20:10:13

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

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)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '8 Aug 2020'	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '17:20'	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '8 Aug 2020 17:20'	System	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'ONCE'	System	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 21:43:31

US3222059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 20:10:37

US3222059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:37

US3222059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '17:00'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:37

US3222059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '08 Aug 2020 17:00'	System	10 Aug 2020 20:10:37

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '08 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '17:05'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '08 Aug 2020 17:05'	System	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 20:11:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 20:11:16
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4)	10 Aug 2020 20:11:16
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 20:10:53
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	10 Aug 2020 20:10:53

US3222059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:11:23

US3222059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	10 Aug 2020 20:11:23

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:04:52', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd61944c4-2283-4cab-b265-907690a3ac3f' User entered 'Yes (Y)'	System	08 Aug 2020 22:05:48
	System	08 Aug 2020 22:05:48

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:05:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd61944c4-2283-4cab-b265-907690a3ac3f' User entered '97.7'	System	08 Aug 2020 22:05:48
	System	08 Aug 2020 22:05:48

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:05:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd61944c4-2283-4cab-b265-907690a3ac3f' User entered 'No (N)'	System	08 Aug 2020 22:05:48
	System	08 Aug 2020 22:05:48

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:05:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd61944c4-2283-4cab-b265-907690a3ac3f' User entered '08 Aug 2020 18:05'	System	08 Aug 2020 22:05:48
	System	08 Aug 2020 22:05:48

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 17:40'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 20:10'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 21:05'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 2'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-09T17:52:05', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '2cad690c-f6ce-47a3-b415-9e085ffa1fdc' User entered 'Yes (Y)'	System	10 Aug 2020 15:24:54
	System	10 Aug 2020 15:24:54

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:24:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '2cad690c-f6ce-47a3-b415-9e085ffa1fdc' User entered '97.1'	System	10 Aug 2020 15:24:54
	System	10 Aug 2020 15:24:54

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:24:33', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '2cad690c-f6ce-47a3-b415-9e085ffa1fdc' User entered 'No (N)'	System	10 Aug 2020 15:24:54
	System	10 Aug 2020 15:24:54

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:24:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '2cad690c-f6ce-47a3-b415-9e085ffa1fdc' User entered '10 Aug 2020 11:24'	System	10 Aug 2020 15:24:54
	System	10 Aug 2020 15:24:54

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 3'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:06:34', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b4453c6e-672c-4885-a968-ec4ba0530bfa' User entered 'Yes (Y)'	System	10 Aug 2020 22:06:56
	System	10 Aug 2020 22:06:56

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:06:43', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b4453c6e-672c-4885-a968-ec4ba0530bfa' User entered '97.7'	System	10 Aug 2020 22:06:56
	System	10 Aug 2020 22:06:56

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:06:47', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b4453c6e-672c-4885-a968-ec4ba0530bfa' User entered 'No (N)'	System	10 Aug 2020 22:06:56
	System	10 Aug 2020 22:06:56

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:06:51', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b4453c6e-672c-4885-a968-ec4ba0530bfa' User entered '10 Aug 2020 18:06'	System	10 Aug 2020 22:06:56
	System	10 Aug 2020 22:06:56

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 4'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:03:17', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '60d8ac72-4aae-4a10-a011-9c6f21a2442c' User entered 'Yes (Y)'	System	11 Aug 2020 22:04:09
	System	11 Aug 2020 22:04:09

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:03:59', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '60d8ac72-4aae-4a10-a011-9c6f21a2442c' User entered '97.6'	System	11 Aug 2020 22:04:09
	System	11 Aug 2020 22:04:09

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:03', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '60d8ac72-4aae-4a10-a011-9c6f21a2442c' User entered 'No (N)'	System	11 Aug 2020 22:04:09
	System	11 Aug 2020 22:04:09

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '60d8ac72-4aae-4a10-a011-9c6f21a2442c' User entered '11 Aug 2020 18:04'	System	11 Aug 2020 22:04:09
	System	11 Aug 2020 22:04:09

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 5'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:23:41', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '322c2c90-bd4f-4e9a-9a1d-b98cf15c3291' User entered 'Yes (Y)'	System	12 Aug 2020 22:24:01
	System	12 Aug 2020 22:24:01

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:23:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '322c2c90-bd4f-4e9a-9a1d-b98cf15c3291' User entered '97.6'	System	12 Aug 2020 22:24:01
	System	12 Aug 2020 22:24:01

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:23:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '322c2c90-bd4f-4e9a-9a1d-b98cf15c3291'	System	12 Aug 2020 22:24:01
User entered 'No (N)'	System	12 Aug 2020 22:24:01

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:23:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '322c2c90-bd4f-4e9a-9a1d-b98cf15c3291'	System	12 Aug 2020 22:24:01
User entered '12 Aug 2020 18:23'	System	12 Aug 2020 22:24:01

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 6'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:13:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cf901c9-1d5c-43b2-9695-117494183677' User entered 'Yes (Y)'	System	13 Aug 2020 22:13:59
	System	13 Aug 2020 22:13:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:13:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cf901c9-1d5c-43b2-9695-117494183677' User entered '97.4'	System	13 Aug 2020 22:13:59
	System	13 Aug 2020 22:13:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:13:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cf901c9-1d5c-43b2-9695-117494183677'	System	13 Aug 2020 22:13:59
User entered 'No (N)'	System	13 Aug 2020 22:13:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:13:56', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cf901c9-1d5c-43b2-9695-117494183677' User entered '13 Aug 2020 18:13'	System	13 Aug 2020 22:13:59
	System	13 Aug 2020 22:13:59

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 7'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:45:36', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f97fbb50-566c-47dd-88d5-a75e2bd5a904' User entered 'Yes (Y)'	System	14 Aug 2020 23:46:00
	System	14 Aug 2020 23:46:00

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:45:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f97fbb50-566c-47dd-88d5-a75e2bd5a904' User entered '97.4'	System	14 Aug 2020 23:46:00
	System	14 Aug 2020 23:46:00

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:45:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f97fbb50-566c-47dd-88d5-a75e2bd5a904'	System	14 Aug 2020 23:46:00
User entered 'No (N)'	System	14 Aug 2020 23:46:00

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:45:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f97fbb50-566c-47dd-88d5-a75e2bd5a904'	System	14 Aug 2020 23:46:00
User entered '14 Aug 2020 19:45'	System	14 Aug 2020 23:46:00

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:06:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd8a5bd7e-eb1e-42e5-8142-8d50a12f3f59'	System	08 Aug 2020 22:06:51
User entered 'None (1)'	System	08 Aug 2020 22:06:51

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:06:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd8a5bd7e-eb1e-42e5-8142-8d50a12f3f59'	System	08 Aug 2020 22:06:51
User entered 'No (N)'	System	08 Aug 2020 22:06:51

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:06:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd8a5bd7e-eb1e-42e5-8142-8d50a12f3f59' User entered 'No (N)'	System	08 Aug 2020 22:06:51
	System	08 Aug 2020 22:06:51

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:06:37', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd8a5bd7e-eb1e-42e5-8142-8d50a12f3f59'	System	08 Aug 2020 22:06:51
User entered 'None (1)'	System	08 Aug 2020 22:06:51

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:06:47', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd8a5bd7e-eb1e-42e5-8142-8d50a12f3f59' User entered '08 Aug 2020 18:06'	System	08 Aug 2020 22:06:51
	System	08 Aug 2020 22:06:51

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 17:40'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 20:10'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 21:05'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 2'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:24:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '343097e3-30cd-4ca2-9f38-2785ba5c9211' User entered 'None (1)'	System	10 Aug 2020 15:25:19
	System	10 Aug 2020 15:25:19

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:24:58', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '343097e3-30cd-4ca2-9f38-2785ba5c9211' User entered 'No (N)'	System	10 Aug 2020 15:25:19
	System	10 Aug 2020 15:25:19

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:04', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '343097e3-30cd-4ca2-9f38-2785ba5c9211' User entered 'No (N)'	System	10 Aug 2020 15:25:19
	System	10 Aug 2020 15:25:19

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:09', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '343097e3-30cd-4ca2-9f38-2785ba5c9211' User entered 'None (1)'	System	10 Aug 2020 15:25:19
	System	10 Aug 2020 15:25:19

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '343097e3-30cd-4ca2-9f38-2785ba5c9211' User entered '10 Aug 2020 11:25'	System	10 Aug 2020 15:25:19
	System	10 Aug 2020 15:25:19

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 3'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:05', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ea6da823-3e74-4a8a-ba3b-2ba56415b58d' User entered 'None (1)'	System	10 Aug 2020 22:07:24
	System	10 Aug 2020 22:07:24

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:09', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ea6da823-3e74-4a8a-ba3b-2ba56415b58d' User entered 'No (N)'	System	10 Aug 2020 22:07:24
	System	10 Aug 2020 22:07:24

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ea6da823-3e74-4a8a-ba3b-2ba56415b58d' User entered 'No (N)'	System	10 Aug 2020 22:07:24
	System	10 Aug 2020 22:07:24

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ea6da823-3e74-4a8a-ba3b-2ba56415b58d' User entered 'None (1)'	System	10 Aug 2020 22:07:24
	System	10 Aug 2020 22:07:24

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:20', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ea6da823-3e74-4a8a-ba3b-2ba56415b58d' User entered '10 Aug 2020 18:07'	System	10 Aug 2020 22:07:24
	System	10 Aug 2020 22:07:24

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 4'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '038bc943-4d7b-4bcf-b905-f26bbc54db48'	System	11 Aug 2020 22:04:37
User entered 'None (1)'	System	11 Aug 2020 22:04:37

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:21', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '038bc943-4d7b-4bcf-b905-f26bbc54db48' User entered 'No (N)'	System	11 Aug 2020 22:04:37
	System	11 Aug 2020 22:04:37

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:28', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '038bc943-4d7b-4bcf-b905-f26bbc54db48' User entered 'No (N)'	System	11 Aug 2020 22:04:37
	System	11 Aug 2020 22:04:37

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '038bc943-4d7b-4bcf-b905-f26bbc54db48'	System	11 Aug 2020 22:04:37
User entered 'None (1)'	System	11 Aug 2020 22:04:37

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '038bc943-4d7b-4bcf-b905-f26bbc54db48'	System	11 Aug 2020 22:04:37
User entered '11 Aug 2020 18:04'	System	11 Aug 2020 22:04:37

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 5'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:11', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9c3328cf-4056-480c-b048-87908e4ddcc5' User entered 'None (1)'	System	12 Aug 2020 22:24:28
	System	12 Aug 2020 22:24:28

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9c3328cf-4056-480c-b048-87908e4ddcc5' User entered 'No (N)'	System	12 Aug 2020 22:24:28
	System	12 Aug 2020 22:24:28

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9c3328cf-4056-480c-b048-87908e4ddcc5' User entered 'No (N)'	System	12 Aug 2020 22:24:28
	System	12 Aug 2020 22:24:28

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9c3328cf-4056-480c-b048-87908e4ddcc5' User entered 'None (1)'	System	12 Aug 2020 22:24:28
	System	12 Aug 2020 22:24:28

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9c3328cf-4056-480c-b048-87908e4ddcc5' User entered '12 Aug 2020 18:24'	System	12 Aug 2020 22:24:28
	System	12 Aug 2020 22:24:28

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 6'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:14:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5ae1d0bd-acad-4dc2-8d8b-6e78d0aa4a11' User entered 'None (1)'	System	13 Aug 2020 22:15:06
	System	13 Aug 2020 22:15:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:14:51', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5ae1d0bd-acad-4dc2-8d8b-6e78d0aa4a11' User entered 'No (N)'	System	13 Aug 2020 22:15:06
	System	13 Aug 2020 22:15:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:14:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5ae1d0bd-acad-4dc2-8d8b-6e78d0aa4a11' User entered 'No (N)'	System	13 Aug 2020 22:15:06
	System	13 Aug 2020 22:15:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:14:58', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5ae1d0bd-acad-4dc2-8d8b-6e78d0aa4a11' User entered 'None (1)'	System	13 Aug 2020 22:15:06
	System	13 Aug 2020 22:15:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5ae1d0bd-acad-4dc2-8d8b-6e78d0aa4a11'	System	13 Aug 2020 22:15:06
User entered '13 Aug 2020 18:15'	System	13 Aug 2020 22:15:06

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 7'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:05', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '8f5deed3-50a7-47f4-9747-ba43ac225918' User entered 'None (1)'	System	14 Aug 2020 23:46:26
	System	14 Aug 2020 23:46:26

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:11', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '8f5deed3-50a7-47f4-9747-ba43ac225918' User entered 'No (N)'	System	14 Aug 2020 23:46:26
	System	14 Aug 2020 23:46:26

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '8f5deed3-50a7-47f4-9747-ba43ac225918' User entered 'No (N)'	System	14 Aug 2020 23:46:26
	System	14 Aug 2020 23:46:26

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '8f5deed3-50a7-47f4-9747-ba43ac225918' User entered 'None (1)'	System	14 Aug 2020 23:46:26
	System	14 Aug 2020 23:46:26

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '8f5deed3-50a7-47f4-9747-ba43ac225918' User entered '14 Aug 2020 19:46'	System	14 Aug 2020 23:46:26
	System	14 Aug 2020 23:46:26

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:23', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:29', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:44', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5' User entered 'None (0)'	System	08 Aug 2020 22:07:59
	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5'	System	08 Aug 2020 22:07:59
User entered 'No (N)'	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-08T18:07:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ce005f33-e0eb-4cd5-ad93-cf01f5d2e5c5'	System	08 Aug 2020 22:07:59
User entered '08 Aug 2020 18:07'	System	08 Aug 2020 22:07:59

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 17:40'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 20:10'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '08 Aug 2020 21:05'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 2'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:24', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:44', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:54', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:25:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:26:01', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'None (0)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:26:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered 'No (N)'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T11:26:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dcf69dbe-f699-4b00-bc72-ccf0c6b5577a' User entered '10 Aug 2020 11:26'	System	10 Aug 2020 15:26:14
	System	10 Aug 2020 15:26:14

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 3'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:26', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:29', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:32', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:36', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:39', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'None (0)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered 'No (N)'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-10T18:07:54', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '78073aed-01e7-4d7b-8b25-928f14bde27e' User entered '10 Aug 2020 18:07'	System	10 Aug 2020 22:07:56
	System	10 Aug 2020 22:07:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 4'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:47', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:52', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:04:58', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered 'None (0)'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:05:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d'	System	11 Aug 2020 22:05:08
User entered 'No (N)'	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-11T18:05:06', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9d90cc15-b0d7-4984-b835-e3740418a56d' User entered '11 Aug 2020 18:05'	System	11 Aug 2020 22:05:08
	System	11 Aug 2020 22:05:08

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 5'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'None (0)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered 'No (N)'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-12T18:24:56', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ca8f317-a039-484c-869c-56c4e4bf976d' User entered '12 Aug 2020 18:24'	System	12 Aug 2020 22:24:58
	System	12 Aug 2020 22:24:58

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 6'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:27', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'None (0)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:36', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4' User entered 'No (N)'	System	13 Aug 2020 22:16:13
	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-13T18:15:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'dec4c24c-97ea-467a-b1fb-d62e4c93b0e4'	System	13 Aug 2020 22:16:13
User entered '13 Aug 2020 18:15'	System	13 Aug 2020 22:16:13

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 7'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:29', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:32', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:39', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'None (0)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:48', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered 'No (N)'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-08-14T19:46:51', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5f901e70-314a-4f83-9208-3296b892d66f' User entered '14 Aug 2020 19:46'	System	14 Aug 2020 23:46:56
	System	14 Aug 2020 23:46:56

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 21:43:31

US3222059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:01:30

US3222059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Aug 2020'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:01:30

US3222059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:01:30

US3222059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:01:30

US3222059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:01:35

US3222059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Sep 2020 18:01:35

US3222059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:02

US3222059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '23 Aug 2020'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:02

US3222059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:02

US3222059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:02

US3222059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:07

US3222059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Sep 2020 18:02:07

US3222059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:27

US3222059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '30 Aug 2020'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:27

US3222059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:27

US3222059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:02:27

US3222059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:09:57

US3222059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Sep 2020 18:09:57

US3222059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:10:13

US3222059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:26:36
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		16 Sep 2020 23:49:08
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit 2 is OOW due SAE. Deviation will be reported. ' (Site from System).	Thais Truffa (b) (4)	14 Sep 2020 18:10:29
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 18:10:13
User entered '14 Sep 2020'	Thais Truffa (b) (4)	14 Sep 2020 18:10:13

US3222059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Clinic (Clinic)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:10:13

US3222059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'VISIT2'	System	14 Sep 2020 18:10:13

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '14 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '13:06'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '14 Sep 2020 13:06'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '36.7' C	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '51'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'bpm'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '17'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'breaths/min'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '159'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '60'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '14 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '14:16'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '14 Sep 2020 14:16'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '36.6' C	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '54'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'bpm'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '17'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'breaths/min'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '134'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '62'	Albert Garcia (b) (4)	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'mmHg'	System	14 Oct 2020 15:13:55

US3222059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:14:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '14 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:14:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

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)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	(b) (4)	
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'PAGE HAS BEEN UPDATED AS DELAYED.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:47:06
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	Albert Garcia (b) (4)	02 Dec 2020 13:30:05
User entered '14 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:04:41
	Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '13:45'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '14 Sep 2020 13:45'	System	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Thais Truffa (b) (4)	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'ONCE'	System	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 18:11:07

US3222059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:14:22

US3222059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '14 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:14:22

US3222059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '13:21'	Albert Garcia (b) (4)	14 Oct 2020 15:14:22

US3222059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '14 Sep 2020 13:21'	System	14 Oct 2020 15:14:22

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '13:27'	Albert Garcia (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '14 Sep 2020 13:27'	System	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:14:34

US3222059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:14:40

US3222059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Oct 2020 15:14:40

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:16:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bfd5f79-1d2c-4fd9-b897-335c26a09d26' User entered 'Yes (Y)'	System	14 Sep 2020 18:17:17
	System	14 Sep 2020 18:17:17

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:16:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bfd5f79-1d2c-4fd9-b897-335c26a09d26' User entered '98.0'	System	14 Sep 2020 18:17:17
	System	14 Sep 2020 18:17:17

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:16:59', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bfd5f79-1d2c-4fd9-b897-335c26a09d26' User entered 'No (N)'	System	14 Sep 2020 18:17:17
	System	14 Sep 2020 18:17:17

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bfd5f79-1d2c-4fd9-b897-335c26a09d26' User entered '14 Sep 2020 14:17'	System	14 Sep 2020 18:17:17
	System	14 Sep 2020 18:17:17

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 14:05'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 16:35'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:26:27', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0eefe34a-b93d-4e6c-a3dd-278fee4cdb70' User entered 'Yes (Y)'	System	14 Sep 2020 22:26:58
	System	14 Sep 2020 22:26:58

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:26:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0eefe34a-b93d-4e6c-a3dd-278fee4cdb70' User entered '98.1'	System	14 Sep 2020 22:26:58
	System	14 Sep 2020 22:26:58

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:26:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0eefe34a-b93d-4e6c-a3dd-278fee4cdb70' User entered 'No (N)'	System	14 Sep 2020 22:26:58
	System	14 Sep 2020 22:26:58

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:26:56', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0eefe34a-b93d-4e6c-a3dd-278fee4cdb70'	System	14 Sep 2020 22:26:58
User entered '14 Sep 2020 18:26'	System	14 Sep 2020 22:26:58

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 17:30'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 2'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 3'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:04', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '52140b4a-d41d-4399-9dc0-178af3ed0306' User entered 'Yes (Y)'	System	17 Sep 2020 15:37:36
	System	17 Sep 2020 15:37:36

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '52140b4a-d41d-4399-9dc0-178af3ed0306' User entered '98.0'	System	17 Sep 2020 15:37:36
	System	17 Sep 2020 15:37:36

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:24', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '52140b4a-d41d-4399-9dc0-178af3ed0306' User entered 'No (N)'	System	17 Sep 2020 15:37:36
	System	17 Sep 2020 15:37:36

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:34', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '52140b4a-d41d-4399-9dc0-178af3ed0306' User entered '17 Sep 2020 11:37'	System	17 Sep 2020 15:37:36
	System	17 Sep 2020 15:37:36

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 4'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:00:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4f23e603-3454-4e4e-bd13-789638672e42' User entered 'Yes (Y)'	System	17 Sep 2020 16:02:07
	System	17 Sep 2020 16:02:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:09', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4f23e603-3454-4e4e-bd13-789638672e42' User entered '97.8'	System	17 Sep 2020 16:02:07
	System	17 Sep 2020 16:02:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4f23e603-3454-4e4e-bd13-789638672e42' User entered 'No (N)'	System	17 Sep 2020 16:02:07
	System	17 Sep 2020 16:02:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4f23e603-3454-4e4e-bd13-789638672e42' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 16:02:07
	System	17 Sep 2020 16:02:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 5'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:28:43', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'bb693615-0c7a-40d9-87ee-59246a8fe3b0' User entered 'Yes (Y)'	System	18 Sep 2020 16:29:07
	System	18 Sep 2020 16:29:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:28:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'bb693615-0c7a-40d9-87ee-59246a8fe3b0' User entered '97.8'	System	18 Sep 2020 16:29:07
	System	18 Sep 2020 16:29:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:28:59', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'bb693615-0c7a-40d9-87ee-59246a8fe3b0'	System	18 Sep 2020 16:29:07
User entered 'No (N)'	System	18 Sep 2020 16:29:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:03', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'bb693615-0c7a-40d9-87ee-59246a8fe3b0' User entered '18 Sep 2020 12:29'	System	18 Sep 2020 16:29:07
	System	18 Sep 2020 16:29:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 6'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:21', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'c32fed71-3056-4fee-a48a-0e24b43be2e7' User entered 'Yes (Y)'	System	19 Sep 2020 17:08:45
	System	19 Sep 2020 17:08:45

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:34', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'c32fed71-3056-4fee-a48a-0e24b43be2e7' User entered '98.0'	System	19 Sep 2020 17:08:45
	System	19 Sep 2020 17:08:45

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'c32fed71-3056-4fee-a48a-0e24b43be2e7' User entered 'No (N)'	System	19 Sep 2020 17:08:45
	System	19 Sep 2020 17:08:45

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'c32fed71-3056-4fee-a48a-0e24b43be2e7' User entered '19 Sep 2020 13:08'	System	19 Sep 2020 17:08:45
	System	19 Sep 2020 17:08:45

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 7'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:54:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6e3f9a73-3382-4dfe-a1fe-d3998e2c51c7' User entered 'Yes (Y)'	System	20 Sep 2020 22:55:07
	System	20 Sep 2020 22:55:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:54:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6e3f9a73-3382-4dfe-a1fe-d3998e2c51c7' User entered '97.6'	System	20 Sep 2020 22:55:07
	System	20 Sep 2020 22:55:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6e3f9a73-3382-4dfe-a1fe-d3998e2c51c7' User entered 'No (N)'	System	20 Sep 2020 22:55:07
	System	20 Sep 2020 22:55:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:04', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6e3f9a73-3382-4dfe-a1fe-d3998e2c51c7' User entered '20 Sep 2020 18:55'	System	20 Sep 2020 22:55:07
	System	20 Sep 2020 22:55:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '14152709-5933-4e8a-a24e-68a7b048f6d9'	System	14 Sep 2020 18:17:58
User entered 'None (1)'	System	14 Sep 2020 18:17:58

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '14152709-5933-4e8a-a24e-68a7b048f6d9' User entered 'No (N)'	System	14 Sep 2020 18:17:58
	System	14 Sep 2020 18:17:58

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '14152709-5933-4e8a-a24e-68a7b048f6d9' User entered 'No (N)'	System	14 Sep 2020 18:17:58
	System	14 Sep 2020 18:17:58

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:51', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '14152709-5933-4e8a-a24e-68a7b048f6d9'	System	14 Sep 2020 18:17:58
User entered 'None (1)'	System	14 Sep 2020 18:17:58

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:17:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '14152709-5933-4e8a-a24e-68a7b048f6d9'	System	14 Sep 2020 18:17:58
User entered '14 Sep 2020 14:17'	System	14 Sep 2020 18:17:58

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 14:05'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 16:35'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:32', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd473ea54-b756-4af7-94bd-2e3543d11567' User entered 'None (1)'	System	14 Sep 2020 22:27:37
	System	14 Sep 2020 22:27:37

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd473ea54-b756-4af7-94bd-2e3543d11567' User entered 'No (N)'	System	14 Sep 2020 22:27:37
	System	14 Sep 2020 22:27:37

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:13', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd473ea54-b756-4af7-94bd-2e3543d11567' User entered 'No (N)'	System	14 Sep 2020 22:27:37
	System	14 Sep 2020 22:27:37

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd473ea54-b756-4af7-94bd-2e3543d11567' User entered 'None (1)'	System	14 Sep 2020 22:27:37
	System	14 Sep 2020 22:27:37

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'd473ea54-b756-4af7-94bd-2e3543d11567' User entered '14 Sep 2020 18:27'	System	14 Sep 2020 22:27:37
	System	14 Sep 2020 22:27:37

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 17:30'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 2'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 3'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:40', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cb66c64-01e5-4a24-8403-1aa49a6ff01a' User entered 'None (1)'	System	17 Sep 2020 15:38:00
	System	17 Sep 2020 15:38:00

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:44', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cb66c64-01e5-4a24-8403-1aa49a6ff01a' User entered 'No (N)'	System	17 Sep 2020 15:38:00
	System	17 Sep 2020 15:38:00

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:47', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cb66c64-01e5-4a24-8403-1aa49a6ff01a' User entered 'No (N)'	System	17 Sep 2020 15:38:00
	System	17 Sep 2020 15:38:00

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:51', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cb66c64-01e5-4a24-8403-1aa49a6ff01a' User entered 'None (1)'	System	17 Sep 2020 15:38:00
	System	17 Sep 2020 15:38:00

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:37:55', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0cb66c64-01e5-4a24-8403-1aa49a6ff01a' User entered '17 Sep 2020 11:37'	System	17 Sep 2020 15:38:00
	System	17 Sep 2020 15:38:00

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 4'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '1e095f24-1a6b-49d3-952d-c93c5a31dac3' User entered 'None (1)'	System	17 Sep 2020 16:02:42
	System	17 Sep 2020 16:02:42

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:28', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '1e095f24-1a6b-49d3-952d-c93c5a31dac3' User entered 'No (N)'	System	17 Sep 2020 16:02:42
	System	17 Sep 2020 16:02:42

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '1e095f24-1a6b-49d3-952d-c93c5a31dac3' User entered 'No (N)'	System	17 Sep 2020 16:02:42
	System	17 Sep 2020 16:02:42

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:34', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '1e095f24-1a6b-49d3-952d-c93c5a31dac3' User entered 'None (1)'	System	17 Sep 2020 16:02:42
	System	17 Sep 2020 16:02:42

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:37', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '1e095f24-1a6b-49d3-952d-c93c5a31dac3' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 16:02:42
	System	17 Sep 2020 16:02:42

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 5'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b5b3a0e2-73f6-4fb8-b547-170e04bdb073'	System	18 Sep 2020 16:29:32
User entered 'None (1)'	System	18 Sep 2020 16:29:32

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b5b3a0e2-73f6-4fb8-b547-170e04bdb073' User entered 'No (N)'	System	18 Sep 2020 16:29:32
	System	18 Sep 2020 16:29:32

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b5b3a0e2-73f6-4fb8-b547-170e04bdb073' User entered 'No (N)'	System	18 Sep 2020 16:29:32
	System	18 Sep 2020 16:29:32

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:23', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b5b3a0e2-73f6-4fb8-b547-170e04bdb073' User entered 'None (1)'	System	18 Sep 2020 16:29:32
	System	18 Sep 2020 16:29:32

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:26', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b5b3a0e2-73f6-4fb8-b547-170e04bdb073' User entered '18 Sep 2020 12:29'	System	18 Sep 2020 16:29:32
	System	18 Sep 2020 16:29:32

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 6'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '39615591-31cd-4656-8125-cc89a8f61233'	System	19 Sep 2020 17:09:09
User entered 'None (1)'	System	19 Sep 2020 17:09:09

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:54', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '39615591-31cd-4656-8125-cc89a8f61233' User entered 'No (N)'	System	19 Sep 2020 17:09:09
	System	19 Sep 2020 17:09:09

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:08:58', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '39615591-31cd-4656-8125-cc89a8f61233' User entered 'No (N)'	System	19 Sep 2020 17:09:09
	System	19 Sep 2020 17:09:09

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '39615591-31cd-4656-8125-cc89a8f61233'	System	19 Sep 2020 17:09:09
User entered 'None (1)'	System	19 Sep 2020 17:09:09

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '39615591-31cd-4656-8125-cc89a8f61233' User entered '19 Sep 2020 13:09'	System	19 Sep 2020 17:09:09
	System	19 Sep 2020 17:09:09

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 7'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:11', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f78b1fb1-8997-4a09-917a-785bfe8dfa19' User entered 'None (1)'	System	20 Sep 2020 22:55:27
	System	20 Sep 2020 22:55:27

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f78b1fb1-8997-4a09-917a-785bfe8dfa19' User entered 'No (N)'	System	20 Sep 2020 22:55:27
	System	20 Sep 2020 22:55:27

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f78b1fb1-8997-4a09-917a-785bfe8dfa19' User entered 'No (N)'	System	20 Sep 2020 22:55:27
	System	20 Sep 2020 22:55:27

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f78b1fb1-8997-4a09-917a-785bfe8dfa19' User entered 'None (1)'	System	20 Sep 2020 22:55:27
	System	20 Sep 2020 22:55:27

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f78b1fb1-8997-4a09-917a-785bfe8dfa19' User entered '20 Sep 2020 18:55'	System	20 Sep 2020 22:55:27
	System	20 Sep 2020 22:55:27

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:08', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:13', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:20', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:30', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'None (0)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered 'No (N)'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T14:18:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '3e588a07-e7e3-4b8f-9d07-2770f5fa8093' User entered '14 Sep 2020 14:18'	System	14 Sep 2020 18:18:52
	System	14 Sep 2020 18:18:52

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 14:05'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 16:35'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:41', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:45', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:48', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:27:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'None (0)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:28:01', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered 'No (N)'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-14T18:28:06', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '236c6412-7d5c-4b3e-ab0d-2ad1cdd07c0d' User entered '14 Sep 2020 18:28'	System	14 Sep 2020 22:28:11
	System	14 Sep 2020 22:28:11

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '14 Sep 2020 17:30'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 2'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 3'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:02', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:04', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'None (0)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:39', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered 'No (N)'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T11:38:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'ad84ebd7-833d-465f-8bfe-99171352839a' User entered '17 Sep 2020 11:38'	System	17 Sep 2020 15:38:49
	System	17 Sep 2020 15:38:49

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 4'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:43', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-ae3e-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:54', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:01:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:02:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered 'None (0)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:02:04', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-ae3e-c261daf2f941' User entered 'No (N)'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-17T12:02:08', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '261f3e36-7d1b-463b-aefe-c261daf2f941' User entered '17 Sep 2020 12:02'	System	17 Sep 2020 16:03:28
	System	17 Sep 2020 16:03:28

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 5'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:46', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:50', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'None (0)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:29:58', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08' User entered 'No (N)'	System	18 Sep 2020 16:30:07
	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-18T12:30:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6d68ccae-3923-413e-b46f-9b2687f2ff08'	System	18 Sep 2020 16:30:07
User entered '18 Sep 2020 12:30'	System	18 Sep 2020 16:30:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 6'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:18', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:26', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'None (0)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered 'No (N)'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-19T13:09:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'efcf852d-43a9-4aed-b643-b9c2bcc16b20' User entered '19 Sep 2020 13:09'	System	19 Sep 2020 17:09:45
	System	19 Sep 2020 17:09:45

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	14 Sep 2020 18:11:07
User entered 'Day 7'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:53', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:55:56', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:56:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:56:03', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:56:06', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'None (0)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:56:11', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered 'No (N)'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-09-20T18:56:13', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'eb18b73f-36f2-4c68-8b73-afd3b8413811' User entered '20 Sep 2020 18:56'	System	20 Sep 2020 22:56:18
	System	20 Sep 2020 22:56:18

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 18:11:07

US3222059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Jun 2021 14:58:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 18:11:07

US3222059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:09

US3222059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '21 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:15:09

US3222059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:09

US3222059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:15:09

US3222059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:19

US3222059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Oct 2020 15:15:19

US3222059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:34

US3222059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '29 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:15:34

US3222059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:34

US3222059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:15:34

US3222059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:40

US3222059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Oct 2020 15:15:40

US3222059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:54

US3222059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '5 Oct 2020'	(b) (4) Albert Garcia (b) (4)	14 Oct 2020 15:15:54

US3222059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 15:15:54

US3222059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:15:54

US3222059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:00

US3222059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Oct 2020 15:16:00

US3222059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:12

US3222059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '13 Oct 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:16:12

US3222059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:12

US3222059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'VISIT3'	System	14 Oct 2020 15:16:12

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered empty.	System	14 Oct 2020 15:16:18

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06

US3222059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06

US3222059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:22

US3222059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 15:16:22

US3222059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:34

US3222059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '13 Oct 2020'	Albert Garcia (b) (4)	14 Oct 2020 15:16:34

US3222059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered '12:33'	Albert Garcia (b) (4)	14 Oct 2020 15:16:34

US3222059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered '13 Oct 2020 12:33'	System	14 Oct 2020 15:16:34

US3222059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 15:16:46

US3222059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	14 Oct 2020 15:16:46

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 64'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 71'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-10-19T10:28:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '38d34aa4-8f2c-4bd9-927b-61d554a51552'	System	19 Oct 2020 14:28:23
User entered 'No (N)'	System	19 Oct 2020 14:28:23

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-10-19T10:28:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '38d34aa4-8f2c-4bd9-927b-61d554a51552'	System	19 Oct 2020 14:28:23
User entered 'No (N)'	System	19 Oct 2020 14:28:23

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-10-19T10:28:21', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '38d34aa4-8f2c-4bd9-927b-61d554a51552' User entered '19 Oct 2020 10:28:21'	System	19 Oct 2020 14:28:23
	System	19 Oct 2020 14:28:23

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 78'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 92'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-07T23:00:06', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b60762d5-efda-4b99-bf94-2d6314110d01' User entered 'No (N)'	System	08 Nov 2020 04:00:34
	System	08 Nov 2020 04:00:34

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-07T23:00:15', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b60762d5-efda-4b99-bf94-2d6314110d01'	System	08 Nov 2020 04:00:34
User entered 'No (N)'	System	08 Nov 2020 04:00:34

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-07T23:00:29', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b60762d5-efda-4b99-bf94-2d6314110d01' User entered '07 Nov 2020 23:00:29'	System	08 Nov 2020 04:00:34
	System	08 Nov 2020 04:00:34

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 99'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-12T18:25:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6fb73b04-acaf-461a-bfe0-af8fdb0a2717'	System	12 Nov 2020 23:25:50
User entered 'No (N)'	System	12 Nov 2020 23:25:50

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-12T18:25:40', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6fb73b04-acaf-461a-bfe0-af8fdb0a2717'	System	12 Nov 2020 23:25:50
User entered 'No (N)'	System	12 Nov 2020 23:25:50

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-12T18:25:48', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6fb73b04-acaf-461a-bfe0-af8fdb0a2717' User entered '12 Nov 2020 18:25:48'	System	12 Nov 2020 23:25:50
	System	12 Nov 2020 23:25:50

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:06
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered 'Day 106'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Please 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 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 21:43:31

US3222059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:45:29
Data entry locked.	System	08 Aug 2020 21:43:31
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 21:43:31

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-23T11:31:03', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '84e9ad71-0110-4c05-b2f6-4f995eea453d' User entered 'No (N)'	System	23 Nov 2020 16:31:28
	System	23 Nov 2020 16:31:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-23T11:31:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '84e9ad71-0110-4c05-b2f6-4f995eea453d'	System	23 Nov 2020 16:31:28
User entered 'No (N)'	System	23 Nov 2020 16:31:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-11-23T11:31:25', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '84e9ad71-0110-4c05-b2f6-4f995eea453d' User entered '23 Nov 2020 11:31:25'	System	23 Nov 2020 16:31:28
	System	23 Nov 2020 16:31:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-01T16:08:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ea274d4-0efb-465a-a4e5-c3b3baf6ad93'	System	01 Dec 2020 21:08:18
User entered 'No (N)'	System	01 Dec 2020 21:08:18

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-01T16:08:13', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ea274d4-0efb-465a-a4e5-c3b3baf6ad93'	System	01 Dec 2020 21:08:18
User entered 'No (N)'	System	01 Dec 2020 21:08:18

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-01T16:08:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4ea274d4-0efb-465a-a4e5-c3b3baf6ad93' User entered '01 Dec 2020 16:08:16'	System	01 Dec 2020 21:08:18
	System	01 Dec 2020 21:08:18

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-08T23:35:48', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e3ad9e69-d3b2-4230-a3c3-c8d0314679c0'	System	09 Dec 2020 04:36:00
User entered 'No (N)'	System	09 Dec 2020 04:36:00

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-08T23:35:52', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e3ad9e69-d3b2-4230-a3c3-c8d0314679c0'	System	09 Dec 2020 04:36:00
User entered 'No (N)'	System	09 Dec 2020 04:36:00

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-08T23:35:56', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e3ad9e69-d3b2-4230-a3c3-c8d0314679c0' User entered '08 Dec 2020 23:35:56'	System	09 Dec 2020 04:36:00
	System	09 Dec 2020 04:36:00

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-14T10:38:28', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e4132722-af9f-42b9-b734-1c184629df32'	System	14 Dec 2020 15:38:45
User entered 'No (N)'	System	14 Dec 2020 15:38:45

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-14T10:38:38', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e4132722-af9f-42b9-b734-1c184629df32'	System	14 Dec 2020 15:38:45
User entered 'No (N)'	System	14 Dec 2020 15:38:45

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-14T10:38:42', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'e4132722-af9f-42b9-b734-1c184629df32' User entered '14 Dec 2020 10:38:42'	System	14 Dec 2020 15:38:45
	System	14 Dec 2020 15:38:45

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-23T11:25:06', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '13c4356a-23af-4b30-81f8-8c9bb6f53006'	System	23 Dec 2020 16:25:20
User entered 'No (N)'	System	23 Dec 2020 16:25:20

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-23T11:25:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '13c4356a-23af-4b30-81f8-8c9bb6f53006'	System	23 Dec 2020 16:25:20
User entered 'No (N)'	System	23 Dec 2020 16:25:20

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-23T11:25:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '13c4356a-23af-4b30-81f8-8c9bb6f53006'	System	23 Dec 2020 16:25:20
User entered '23 Dec 2020 11:25:14'	System	23 Dec 2020 16:25:20

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-28T10:47:10', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9eb25fb5-a88e-43dd-8c6e-dcd8e15ace2f' User entered 'No (N)'	System	28 Dec 2020 15:47:23
	System	28 Dec 2020 15:47:23

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-28T10:47:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9eb25fb5-a88e-43dd-8c6e-dcd8e15ace2f' User entered 'No (N)'	System	28 Dec 2020 15:47:23

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2020-12-28T10:47:19', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9eb25fb5-a88e-43dd-8c6e-dcd8e15ace2f' User entered '28 Dec 2020 10:47:19'	System	28 Dec 2020 15:47:23

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-04T10:15:07', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b2c39356-c07e-48ed-a31d-9469083946d2'	System	04 Jan 2021 15:15:28
User entered 'No (N)'	System	04 Jan 2021 15:15:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-04T10:15:12', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b2c39356-c07e-48ed-a31d-9469083946d2'	System	04 Jan 2021 15:15:28
User entered 'No (N)'	System	04 Jan 2021 15:15:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-04T10:15:23', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'b2c39356-c07e-48ed-a31d-9469083946d2' User entered '04 Jan 2021 10:15:23'	System	04 Jan 2021 15:15:28
	System	04 Jan 2021 15:15:28

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-11T16:51:40', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '457932c9-1919-41be-acdd-34af6c3c5c75'	System	11 Jan 2021 21:51:52
User entered 'No (N)'	System	11 Jan 2021 21:51:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-11T16:51:44', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '457932c9-1919-41be-acdd-34af6c3c5c75'	System	11 Jan 2021 21:51:52
User entered 'No (N)'	System	11 Jan 2021 21:51:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-11T16:51:49', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '457932c9-1919-41be-acdd-34af6c3c5c75' User entered '11 Jan 2021 16:51:49'	System	11 Jan 2021 21:51:52
	System	11 Jan 2021 21:51:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-18T18:04:24', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5eba7a9a-036a-49ba-84d8-c1993cd319ac' User entered 'No (N)'	System	18 Jan 2021 23:05:01
	System	18 Jan 2021 23:05:01

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-18T18:04:27', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5eba7a9a-036a-49ba-84d8-c1993cd319ac' User entered 'No (N)'	System	18 Jan 2021 23:05:01

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-18T18:04:36', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '5eba7a9a-036a-49ba-84d8-c1993cd319ac' User entered '18 Jan 2021 18:04:36'	System	18 Jan 2021 23:05:01
	System	18 Jan 2021 23:05:01

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-25T11:18:09', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0dcb6834-c49e-4b48-90f8-abea472be9a7'	System	25 Jan 2021 16:19:38
User entered 'No (N)'	System	25 Jan 2021 16:19:38

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-25T11:18:13', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0dcb6834-c49e-4b48-90f8-abea472be9a7'	System	25 Jan 2021 16:19:38
User entered 'No (N)'	System	25 Jan 2021 16:19:38

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-01-25T11:18:24', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '0dcb6834-c49e-4b48-90f8-abea472be9a7' User entered '25 Jan 2021 11:18:24'	System	25 Jan 2021 16:19:38
	System	25 Jan 2021 16:19:38

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-01T11:37:05', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4a2019c1-18b4-4914-af66-07562ae303a5' User entered 'No (N)'	System	01 Feb 2021 16:37:17
	System	01 Feb 2021 16:37:17

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-01T11:37:09', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4a2019c1-18b4-4914-af66-07562ae303a5' User entered 'No (N)'	System	01 Feb 2021 16:37:17
	System	01 Feb 2021 16:37:17

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-01T11:37:14', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '4a2019c1-18b4-4914-af66-07562ae303a5' User entered '01 Feb 2021 11:37:14'	System	01 Feb 2021 16:37:17
	System	01 Feb 2021 16:37:17

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-08T11:21:16', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '7225c7b5-fc85-43c3-8f17-dc1cb3e7727b' User entered 'No (N)'	System	08 Feb 2021 16:21:36
	System	08 Feb 2021 16:21:36

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-08T11:21:20', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '7225c7b5-fc85-43c3-8f17-dc1cb3e7727b' User entered 'No (N)'	System	08 Feb 2021 16:21:36

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-08T11:21:32', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '7225c7b5-fc85-43c3-8f17-dc1cb3e7727b' User entered '08 Feb 2021 11:21:32'	System	08 Feb 2021 16:21:36
	System	08 Feb 2021 16:21:36

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-15T09:55:27', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '64c90966-da3a-4146-b812-4d8097f4ae30'	System	15 Feb 2021 14:55:39
User entered 'No (N)'	System	15 Feb 2021 14:55:39

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-15T09:55:31', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '64c90966-da3a-4146-b812-4d8097f4ae30' User entered 'No (N)'	System	15 Feb 2021 14:55:39

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-15T09:55:35', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '64c90966-da3a-4146-b812-4d8097f4ae30' User entered '15 Feb 2021 09:55:35'	System	15 Feb 2021 14:55:39
	System	15 Feb 2021 14:55:39

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-22T09:00:23', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '134b2d17-0c0d-46d0-a40f-0753781a0e68'	System	22 Feb 2021 14:01:25
User entered 'Yes (Y)'	System	22 Feb 2021 14:01:25

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-22T09:00:32', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '134b2d17-0c0d-46d0-a40f-0753781a0e68'	System	22 Feb 2021 14:01:25
User entered 'No (N)'	System	22 Feb 2021 14:01:25

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-22T09:00:48', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '134b2d17-0c0d-46d0-a40f-0753781a0e68' User entered 'No (N)'	System	22 Feb 2021 14:01:25
	System	22 Feb 2021 14:01:25

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-22T09:00:57', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '134b2d17-0c0d-46d0-a40f-0753781a0e68' User entered 'No (N)'	System	22 Feb 2021 14:01:25
	System	22 Feb 2021 14:01:25

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-02-22T09:01:22', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '134b2d17-0c0d-46d0-a40f-0753781a0e68' User entered '22 Feb 2021 09:01:22'	System	22 Feb 2021 14:01:25
	System	22 Feb 2021 14:01:25

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-02T23:19:04-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '313b31c1-bd87-409b-9521-6037e0aa13ed'	System	03 Mar 2021 04:19:22
User entered 'No (N)'	System	03 Mar 2021 04:19:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-02T23:19:09-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '313b31c1-bd87-409b-9521-6037e0aa13ed'	System	03 Mar 2021 04:19:22
User entered 'No (N)'	System	03 Mar 2021 04:19:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-02T23:19:18-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '313b31c1-bd87-409b-9521-6037e0aa13ed'	System	03 Mar 2021 04:19:22
User entered '02 Mar 2021 23:19:18'	System	03 Mar 2021 04:19:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-08T18:17:33-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '04056e3d-b900-4d58-85c3-3223f7dd368b'	System	08 Mar 2021 23:21:24
User entered 'No (N)'	System	08 Mar 2021 23:21:24

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-08T18:17:38-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '04056e3d-b900-4d58-85c3-3223f7dd368b'	System	08 Mar 2021 23:21:24
User entered 'No (N)'	System	08 Mar 2021 23:21:24

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-08T18:17:50-05:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '04056e3d-b900-4d58-85c3-3223f7dd368b'	System	08 Mar 2021 23:21:24
User entered '08 Mar 2021 18:17:50'	System	08 Mar 2021 23:21:24

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-16T09:36:11-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '56ceb415-77e6-49d4-8a00-b40cbb2f8e1c' User entered 'No (N)'	System	16 Mar 2021 13:36:22
	System	16 Mar 2021 13:36:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-16T09:36:15-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '56ceb415-77e6-49d4-8a00-b40cbb2f8e1c'	System	16 Mar 2021 13:36:22
User entered 'No (N)'	System	16 Mar 2021 13:36:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-16T09:36:19-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '56ceb415-77e6-49d4-8a00-b40cbb2f8e1c' User entered '16 Mar 2021 09:36:19'	System	16 Mar 2021 13:36:22
	System	16 Mar 2021 13:36:22

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-30T10:20:40-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f0810df9-82b2-450b-92ea-738fa7880902'	System	30 Mar 2021 14:20:53
User entered 'No (N)'	System	30 Mar 2021 14:20:53

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-30T10:20:45-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f0810df9-82b2-450b-92ea-738fa7880902'	System	30 Mar 2021 14:20:53
User entered 'No (N)'	System	30 Mar 2021 14:20:53

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-03-30T10:20:49-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: 'f0810df9-82b2-450b-92ea-738fa7880902' User entered '30 Mar 2021 10:20:49'	System	30 Mar 2021 14:20:53
	System	30 Mar 2021 14:20:53

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-05T10:48:41-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '87ae52f8-3e3f-464e-9e2b-19eb71247480'	System	05 Apr 2021 14:48:52
User entered 'No (N)'	System	05 Apr 2021 14:48:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-05T10:48:45-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '87ae52f8-3e3f-464e-9e2b-19eb71247480'	System	05 Apr 2021 14:48:52
User entered 'No (N)'	System	05 Apr 2021 14:48:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-05T10:48:49-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '87ae52f8-3e3f-464e-9e2b-19eb71247480'	System	05 Apr 2021 14:48:52
User entered '05 Apr 2021 10:48:49'	System	05 Apr 2021 14:48:52

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-20T10:58:49-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9dad7238-a55b-4773-ae69-eca8def48a0d'	System	20 Apr 2021 14:59:10
User entered 'No (N)'	System	20 Apr 2021 14:59:10

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-20T10:58:53-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9dad7238-a55b-4773-ae69-eca8def48a0d'	System	20 Apr 2021 14:59:10
User entered 'No (N)'	System	20 Apr 2021 14:59:10

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-20T10:59:02-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '9dad7238-a55b-4773-ae69-eca8def48a0d' User entered '20 Apr 2021 10:59:02'	System	20 Apr 2021 14:59:10
	System	20 Apr 2021 14:59:10

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-30T17:33:35-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bb8ea41-1c3d-483b-9715-2c90a0e9a873'	System	30 Apr 2021 21:33:47
User entered 'No (N)'	System	30 Apr 2021 21:33:47

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Have you been exposed to someone with 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 (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-30T17:33:38-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bb8ea41-1c3d-483b-9715-2c90a0e9a873'	System	30 Apr 2021 21:33:47
User entered 'No (N)'	System	30 Apr 2021 21:33:47

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BC19D8CD-97E8-478D-B539-32B930962334)', Time: '2021-04-30T17:33:43-04:00', User OID: 'PatientReportedOutcome (US3222059)', ODM File OID: '6bb8ea41-1c3d-483b-9715-2c90a0e9a873' User entered '30 Apr 2021 17:33:43'	System	30 Apr 2021 21:33:47
	System	30 Apr 2021 21:33:47

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:45:29

US3222059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 14:58:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:45:29
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:45:29

US3222059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	18 Nov 2020 15:48:32

US3222059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '9 Nov 2020' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 21:52:08
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 10:58:05
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONFIRM CORRECT PD FILED IN CHART' (Site from System).	Alicia Cevera (b) (4)	18 Nov 2020 15:53:33
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 15:48:32
User entered '14 Nov 2020'	Alicia Cevera (b) (4)	18 Nov 2020 15:48:32

US3222059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 15:48:32

US3222059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 15:48:32

US3222059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	18 Nov 2020 15:48:22

US3222059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:06
User entered 'I'	System	18 Nov 2020 15:48:22

US3222059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:26:29

US3222059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:26:29

US3222059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:26:29

US3222059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:26:29

US3222059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:03:52

US3222059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User entered 'I'	System	12 Jan 2021 16:03:52

US3222059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:19:43

US3222059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:19:43

US3222059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:19:43

US3222059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:19:43

US3222059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:20:04

US3222059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User entered 'I'	System	12 Jan 2021 16:20:04

US3222059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Mar 2021 10:26:03

US3222059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '11 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Mar 2021 10:26:03

US3222059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Mar 2021 10:26:03

US3222059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	19 Mar 2021 10:26:03

US3222059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Mar 2021 10:26:10

US3222059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:21
User entered 'I'	System	19 Mar 2021 10:26:10

US3222059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:28:05

US3222059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '18 Mar 2021'	Diana Toney (b) (4)	19 Mar 2021 10:28:05

US3222059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	19 Mar 2021 10:28:05

US3222059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered 'VISIT4'	System	19 Mar 2021 10:28:05

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered empty.	System	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered empty.	System	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered empty.	System	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered empty.	System	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered empty.	System	31 Mar 2021 14:03:50

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52

US3222059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52

US3222059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'No (N)'	Diana Toney (b) (4)	19 Mar 2021 10:28:12

US3222059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:28:12

US3222059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:28:40

US3222059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '18 Mar 2021'	Diana Toney (b) (4)	19 Mar 2021 10:28:40

US3222059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '13:40'	Diana Toney (b) (4)	19 Mar 2021 10:28:40

US3222059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered '18 Mar 2021 13:40'	System	19 Mar 2021 10:28:40

US3222059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:28:46

US3222059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:28:52
User entered 'I'	System	19 Mar 2021 10:28:46

US3222059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:16:36

US3222059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:16:36

US3222059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:16:36

US3222059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:16:36

US3222059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:16:43

US3222059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:16:43

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:08:46

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:08:46

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	19 Jan 2021 21:08:46

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:08:46

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:32:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:31:45

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:49
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) (4), (b) (6)	23 Apr 2021 20:14:19
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:33:03
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 12:32:57
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)	22 Apr 2021 07:13:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:31:45

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Placebo (Placebo)'	Diana Toney (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:34:39
User entered 'Placebo (Placebo)'	Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 01:34:39
User entered 'Placebo (Placebo)'	Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '1'	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 14:58:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '160.0' cm	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '65.5' kg	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '25.58594'	System	19 Jan 2021 21:11:11
DataPoint set to visible.	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '160.0' cm	(b) (4)	
	Diana Toney (b) (4)	19 Jan 2021 21:11:11
	(b) (4)	

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '65.5' kg	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '25.58594'	System	19 Jan 2021 21:11:11
DataPoint set to visible.	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '15:10'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '19 Jan 2021 15:10'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.6' C	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '71'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'bpm'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'breaths/min'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '130'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '73'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '160.0' cm	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '65.5' kg	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 14:58:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '25.58594'	System	19 Jan 2021 21:11:11
DataPoint set to visible.	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '15:55'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '19 Jan 2021 15:55'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.6' C	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '68'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'bpm'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'breaths/min'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '140'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '76'	Diana Toney (b) (4)	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	19 Jan 2021 21:11:11

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:11:21

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:11:21

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mRNA-1273'	System	19 Jan 2021 21:11:44
DataPoint set to visible.	System	19 Jan 2021 21:09:12

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '15:24'	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '19 Jan 2021 15:24'	System	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Left Arm (LEFT ARM)'	Diana Toney (b) (4)	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'ONCE'	System	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:11:44

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:12:20

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:12:20

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14:25'	Diana Toney (b) (4)	19 Jan 2021 21:12:20

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '19 Jan 2021 14:25'	System	19 Jan 2021 21:12:20

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Jan 2021 21:12:35

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19 Jan 2021'	Diana Toney (b) (4)	19 Jan 2021 21:12:35

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14:28'	Diana Toney (b) (4)	19 Jan 2021 21:12:35

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 14:58:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '19 Jan 2021 14:28'	System	19 Jan 2021 21:12:35

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	19 Jan 2021 21:12:43

US3222059

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	19 Jan 2021 21:12:43

US3222059

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:24

US3222059

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:24

US3222059

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:24

US3222059

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:24

US3222059

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:29

US3222059

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	17 Feb 2021 19:39:29

US3222059

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	17 Feb 2021 19:39:29
DataPoint set to visible.	System	17 Feb 2021 19:39:29

US3222059

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:41

US3222059

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:41

US3222059

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:39:41

US3222059

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'OLD29'	System	17 Feb 2021 19:39:41

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '13:36'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '16 Feb 2021 13:36'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'bpm'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'breaths/min'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '120'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:28:05
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 20:18:27
User opened query 'Diastolic Blood Pressure reported System 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).		17 Feb 2021 19:41:09
User entered '58'	(b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '15:11'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '16 Feb 2021 15:11'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'bpm'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'breaths/min'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '115'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:28:12
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Albert Garcia (b) (4) (b) (4)	17 Feb 2021 20:19:03
User opened query 'Diastolic Blood Pressure reported System 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).		17 Feb 2021 19:41:09
User entered '59'	(b) (4), (b) (6)	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mmHg'	System	17 Feb 2021 19:41:09

US3222059

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:29

US3222059

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:29

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'mRNA-1273'	System	17 Feb 2021 19:41:44
DataPoint set to visible.	System	17 Feb 2021 19:39:29

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '14:40'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '16 Feb 2021 14:40'	System	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'ONCE'	System	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 14:58:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 19:41:44

US3222059

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 19:41:48

US3222059

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	17 Feb 2021 19:41:48

US3222059

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:52:22

US3222059

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 09:17:29
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with '1st Call attempted on 2/27 and had to leave message. 2nd attempt on 3/1' (Site from System).	(b) (4), (b) (6)	06 Mar 2021 18:06:28
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Mar 2021 14:52:22
User entered '01 Mar 2021'	(b) (4), (b) (6)	01 Mar 2021 14:52:22

US3222059

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:52:22

US3222059

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 14:58:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:52:22

US3222059

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:29:08

US3222059

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Jun 2021 14:58:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'I'	System	19 Mar 2021 10:29:08

US3222059

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:29:39

US3222059

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '18 Mar 2021'	Diana Toney (b) (4)	19 Mar 2021 10:29:39

US3222059

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	19 Mar 2021 10:29:39

US3222059

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 14:58:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered 'OLD57'	System	19 Mar 2021 10:29:39

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'No (N)'	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered empty.	System	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered empty.	System	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered empty.	System	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered empty.	System	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered empty.	System	19 Mar 2021 10:29:47

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52

US3222059

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 14:58:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52

US3222059

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'No (N)'	Diana Toney (b) (4)	19 Mar 2021 10:29:56

US3222059

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 14:58:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered empty.	Diana Toney (b) (4)	19 Mar 2021 10:29:56

US3222059

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered 'Yes (Y)'	Diana Toney (b) (4)	19 Mar 2021 10:30:26

US3222059

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '18 Mar 2021'	Diana Toney (b) (4)	19 Mar 2021 10:30:26

US3222059

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:43
User entered '13:40'	Diana Toney (b) (4)	19 Mar 2021 10:30:26

US3222059

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 14:58:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:52
User entered '18 Mar 2021 13:40'	System	19 Mar 2021 10:30:26

US3222059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Jun 2021 14:58:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:16
Query 'PV Query: Please add SAE to the EDC as soon as possible. Paper SAE form reported 'New Onset V-fib' although discharge summary reported 'Atrial fibrillation with RVR'. Please clarify and enter SAE into EDC. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 12:40:33
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:34:19
User opened query 'PV Query: Please add SAE to the EDC as soon as possible. Paper SAE form reported 'New Onset V-fib' although discharge summary reported 'Atrial fibrillation with RVR'. Please clarify and enter SAE into EDC. ' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 15:31:40
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 20:11:31

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 21:25:33
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:06
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	16 Sep 2020 12:41:01

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 15:22:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 19:28:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 19:28:36
Data point term sent to Coder	System	10 Nov 2020 19:38:27
DataPoint Un-verified.	Albert Garcia (b) (4)	10 Nov 2020 19:38:26
Coding entries removed.	Albert Garcia (b) (4)	10 Nov 2020 19:38:26
User entered 'NEW ONSET-ATRIAL FIBRILLATION' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 19:38:26
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 15:29:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 15:29:54
Data point term sent to Coder	System	30 Oct 2020 15:28:40
Coding entries removed.	douglas winter (b) (4)	30 Oct 2020 15:28:31
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	douglas winter (b) (4)	30 Oct 2020 15:28:31
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 11:23:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 11:23:54
Data point term sent to Coder	System	15 Sep 2020 16:57:00
User entered 'New onset atrial fibrillation'	douglas winter (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 15:18:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Oct 2020 15:18:50
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:18:50
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 16:56:03
User entered empty.	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:49:08
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 16:56:03
User entered '3 Sep 2020'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 15:18:50
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:18:50
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	15 Sep 2020 16:56:03
User entered '14:17'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:18:50
User entered '3 Sep 2020 14:17'	System	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '5 Sep 2020'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 15:18:50
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:18:50
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Sep 2020 16:56:03
User entered '18:39'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 15:18:50
User entered '5 Sep 2020 18:39'	System	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'PV Query: Please confirm the intensity of the event as grade 4. Was the event life-threatening? If so, please add life-threatening serious criteria. If not, please consider downgrading to grade 3.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:16:44
Query 'PV Query: Please confirm the intensity of the event as grade 4. Was the event life-threatening? If so, please add life-threatening serious criteria. If not, please consider downgrading to grade 3.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 15:19:22
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 15:18:50
	(b) (4)	
User opened query 'PV Query: Please confirm the intensity of the event as grade 4. Was the event life-threatening? If so, please add life-threatening serious criteria. If not, please consider downgrading to grade 3.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 19:59:53
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4)	15 Sep 2020 16:56:03
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'PV Query: As the patient was hospitalized please add hospitalization as additional seriousness criterion for the event new onset Atrial fibrillation.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:16:50
Query 'PV Query: As the patient was hospitalized please add hospitalization as additional seriousness criterion for the event new onset Atrial fibrillation.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 15:19:29
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	12 Oct 2020 15:18:50
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Oct 2020 15:18:50
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 15:18:50
User opened query 'PV Query: As the patient was hospitalized please add hospitalization as additional seriousness criterion for the event new onset Atrial fibrillation.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	24 Sep 2020 20:01:11
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	15 Sep 2020 16:56:03
User entered '0'	douglas winter (b) (4)	15 Sep 2020 16:56:03
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '3 Sep 2020'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '5 Sep 2020'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered empty.	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'I'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:13:51
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 13:02:17
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 13:02:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 13:02:10
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:08:21
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'PV Query: It was reported that the second study medication dose was delayed due to the reported event. Please provide the date that the second dose was administered' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:26:58
Query 'PV Query: It was reported that the second study medication dose was delayed due to the reported event. Please provide the date that the second dose was administered' answered with 'DOSE WAS GIVEN 14SEP2020 AS NOTED ON VISIT 2 eCRF's.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 13:59:06
User opened query 'PV Query: It was reported that the second study medication dose was delayed due to the reported event. Please provide the date that the second dose was administered' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 19:58:00
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 13:15:41
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'PLEASE REVIEW VISIT 2 EXPOSURE PAGE. SUBJECT RECEIVED SECOND VACCINE, BUT WITH DELAY. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	04 Dec 2020 18:00:56
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 14:49:57
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:29:27
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:29:27
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 19:19:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:19:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:56:06
User entered 'I'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered '0'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:25:33
User entered empty.	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS CALLED BY THE PATIENT TONIGHT 06/SEP/2020 SUBJECT WENT TO A REGULARLY SCHEDULED DOCTOR'S APPOINTMENT ON 03/SEP/2020, AND HER PHYSICIAN LISTENED TO HER BREATH SOUNDS AND THEN APICAL AND SAID YOUR HEART RATE IS TOO FAST AND SENT HER TO THE EMERGENCY ROOM. WHERE THEY DIAGNOSED HER WITH NEW ONSET OF A-FIB. SHE STAYED FROM 03/SEP/2020 AND DISCHARGED ON 05/SEP/2020. I AM REQUESTING THE DISCHARGE SUMMARY DIAGNOSED WITH ATRIAL FIBRILLATION WITH RVR, AND ESSENTIAL HYPERTENSION. SHE WAS EVALUATED BY A CARDIOLOGIS WHO PRESCRIBED HER ELIQUIS AND PRESCRIBED HER METOPROLOL WITH INSTRUCTIONS NOT TO TAKE WHEN HEART RATES IS LESS THAN 58 OR BLOOD PRESSURE IS LESS THAN 110 SYSTOLIC, HEART RYTHM CONFIRMED BY EKG PRIOR TO DISCHARGE. PCR WAS COLLECT AND NEGATIVE FOR COVID-19. LABS: WBC HIGH 10.9X1083/MICROL 04/SEP/2020 RBC LOW 4.16X1086/MICROL 04/SEP/2020 GLUCOSE HIGH 109 M/DL 04/SEP/2020 TREATMENT: CARDIOLOGIST TREATED PATIENT WITH UNSPECIFIED ANTIARRHYTHMICS AND ELIQUIS FOR CLOT PREVENTION. SHE WAS CONFIRMED STABLE THE FOLLOWING DAY FOR DISCHARGE.' (WR#5445128)	System	11 Jun 2021 14:45:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: SAE Narrative = EKG PRIOR TO DISCHARGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:05:33

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = EKG PRIOR TO DISCHARGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'DISCHARGE NOTE STATES THE EKG WAS NOTED PRIOR TO RELEASE, HOWEVER WE DO NOT HAVE A COPY OF THAT EKG IN THE DISCHARGE PAPERWORK. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	09 Dec 2020 19:09:09
User opened query 'Per DM CLR: SAE Narrative = EKG PRIOR TO DISCHARGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:14:31
User closed query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:44:02
User closed query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:43:48
User closed query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:43:44
User closed query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 15:43:36
Query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' answered with 'THERE IS NO INDICATION OF SARS TESTING CONDUCTED AT THE HOSPITAL. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:21:34
Query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' answered with 'THIS CANNOT BE CONFIRMED AS THE DISCHARGE SUMMARY DOES NOT INCLUDE EKG RESULTS. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:15:10

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' answered with 'ALL ASSOCIATED SEESEEMENT RESULTS ARE PRESENT IN THE SUBJECT CHART.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:14:42
Query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' answered with 'SAE IS FOR SUDDEN ONSET A-FIB, NOT HYPERTENSION. PLEASE REVIEW. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 13:11:11
User opened query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:28:18
User opened query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:28:13
User opened query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:28:05
User opened query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:27:58
User closed query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:36:48
User closed query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:31:58
User closed query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:31:47
User closed query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 16:31:38

PRODUCTION RELEASE (v12.003
EAB) (1725)

2056 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	25 Nov 2020 15:09:45
User entered 'I WAS CALLED BY THE PATIENT TONIGHT 06/SEP/2020 SUBJECT WENT TO A REGULARLY SCHEDULED DOCTOR'S APPOINTMENT ON 03/SEP/2020, AND HER PHYSICIAN LISTENED TO HER BREATH SOUNDS AND THEN APICAL AND SAID YOUR HEART RATE IS TOO FAST AND SENT HER TO THE EMERGENCY ROOM. WHERE THEY DIAGNOSED HER WITH NEW ONSET OF A-FIB. SHE STAYED FROM 03/SEP/2020 AND DISCHARGED ON 05/SEP/2020. I AM REQUESTING THE DISCHARGE SUMMARY DIAGNOSED WITH ATRIAL FIBRILLATION WITH RVR, AND ESSENTIAL HYPERTENSION. SHE WAS EVALUATED BY A CARDIOLOGIS WHO PRESCRIBED HER ELIQUIS AND PRESCRIBED HER METOPROLOL WITH INSTRUCTIONS NOT TO TAKE WHEN HEART RATES IS LESS THAN 58 OR BLOOD PRESSURE IS LESS THAN 110 SYSTOLIC, HEART RYTHM CONFIRMED BY EKG PRIOR TO DISCHARGE. PCR WAS COLLECT AND NEGATIVE FOR COVID-19. Labs: WBC HIGH 10.9X1083/MICROL 04/SEP/2020 RBC LOW 4.16X1086/MICROL 04/SEP/2020 GLUCOSE HIGH 109 M/DL 04/SEP/2020 TREATMENT: CARDIOLOGIST TREATED PATIENT WITH UNSPECIFIED ANTIARRHYTHMICS AND ELIQUIS FOR CLOT PREVENTION. SHE WAS CONFIRMED STABLE THE FOLLOWING DAY FOR DISCHARGE.' reason for change: Data Entry Error	douglas winter (b) (4)	25 Nov 2020 15:09:38

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = Diagnosed with ESSENTIAL HYPERTENSION. However, this is not recorded in the AE eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:59:31
Query 'Per DM CLR: SAE Narrative = Diagnosed with ESSENTIAL HYPERTENSION. However, this is not recorded in the AE eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'UPDATED' (Site from DM).	douglas winter (b) (4)	24 Nov 2020 22:44:42
Query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' answered with 'ADDED AE' (Site from Safety).	douglas winter (b) (4)	24 Nov 2020 22:44:20
User entered 'I WAS CALLED BY THE PATIENT TONIGHT 06/SEP/2020 SUBJECT WENT TO A REGULARLY SCHEDULED DOCTOR'S APPOINTMENT ON 03/SEP/2020, AND HER PHYSICIAN LISTENED TO HER BREATH SOUNDS AND THEN APICAL AND SAID YOUR HEART RATE IS TOO FAST AND SENT HER TO THE EMERGENCY ROOM. WHERE THEY DIAGNOSED HER WITH NEW ONSET OF V-FIB. SHE STAYED FROM 03/SEP/2020 AND DISCHARGED ON 05/SEP/2020. I AM REQUESTING THE DISCHARGE SUMMARY DIAGNOSED WITH ATRIAL FIBRILLATION WITH RVR, AND ESSENTIAL HYPERTENSION. SHE WAS EVALUATED BY A CARDIOLOGIS WHO PRESCRIBED HER ELIQUIS AND PRESCRIBED HER METOPROLOL WITH INSTRUCTIONS NOT TO TAKE WHEN HEART RATES IS LESS THAN 58 OR BLOOD PRESSURE IS LESS THAN 110 SYSTOLIC, HEART RYTHM CONFIRMED BY EKG PRIOR TO DISCHARGE. PCR WAS COLLECT AND NEGATIVE FOR COVID-19. SHE WAS DISCHARGED OVER TO HER DAUGHTER AND IN STABLE CONDITION.' reason for change: Data Entry Error	douglas winter (b) (4)	24 Nov 2020 22:13:31

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' answered with 'PCR WAS COLLECT AND NEGATIVE FOR COVID-19' (Site from Safety).	douglas winter (b) (4) (b) (4)	24 Nov 2020 22:12:45
Query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' answered with 'CONFIRMED BY EKG' (Site from Safety).	douglas winter (b) (4) (b) (4)	24 Nov 2020 22:09:33
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	24 Nov 2020 22:09:19
User entered 'I WAS CALLED BY THE PATIENT TONIGHT 06/SEP/2020 SUBJECT WENT TO A REGULARLY SCHEDULED DOCTOR'S APPOINTMENT ON 03/SEP/2020, AND HER PHYSICIAN LISTENED TO HER BREATH SOUNDS AND THEN APICAL AND SAID YOUR HEART RATE IS TOO FAST AND SENT HER TO THE EMERGENCY ROOM. WHERE THEY DIAGNOSED HER WITH NEW ONSET OF V-FIB. SHE STAYED FROM 03/SEP/2020 AND DISCHARGED ON 05/SEP/2020. I AM REQUESTING THE DISCHARGE SUMMARY DIAGNOSED WITH ATRIAL FIBRILLATION WITH RVR, AND ESSENTIAL HYPERTENSION. SHE WAS EVALUATED BY A CARDIOLOGIS WHO PRESCRIBED HER ELIQUIS AND PRESCRIBED HER METOPROLOL WITH INSTRUCTIONS NOT TO TAKE WHEN HEART RATES IS LESS THAN 58 OR BLOOD PRESSURE IS LESS THAN 110 SYSTOLIC, HEART RYTHM CONFIRMED BY EKG PRIOR TO DISCHARGE. SHE WAS DISCHARGED OVER TO HER DAUGHTER AND IN STABLE CONDITION.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Nov 2020 22:09:19
User opened query 'Per DM CLR: SAE Narrative = Diagnosed with ESSENTIAL HYPERTENSION. However, this is not recorded in the AE eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	22 Nov 2020 23:36:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

2059 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = Patient was diagnosed with new onset V-Fib. However, AE term is Atrial Fibrillation. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:36:08
User opened query 'PV Query: Please confirm that essential hypertension meets criteria of AE/SAE. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:26:54
User opened query 'PV Query: Please provide any investigations of SARS-COV-2 status during the event (or hospitalization), if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:26:40
User opened query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:26:22
User opened query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 16:25:58
User closed query 'PV Query: Please clarify if potassium value 0.4 mmol/L was a typo. Please correct as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:13:07
User closed query 'PV Query: The case narrative section refers to V-fib. Please confirm if the subject ever had a rhythm of V-fib or update the narrative.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:13:04
User closed query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:13:01
User closed query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:11:47
User closed query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:11:43

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The case narrative section refers to Albert Garcia V-fib. Please confirm if the subject ever had a rhythm of V-fib or update the narrative.' answered with 'THIS IS INCORRECT. A-FIB IS THE CORRECT DIAGNOSES' (Site from Safety).	(b) (4)	10 Nov 2020 19:44:02
Query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' answered with 'WBC - 10.9 X10 ³ /microL HIGH RBC - 4.16 x 10 ⁶ /microl LOW hct - 40.7% Platelet - 2328 x 10 ³ /microL REFERENCE RANGES WERE NOT PROVIDED IIN THIS REPORT.' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:43:35
Query 'PV Query: Please clarify if potassium value 0.4 mmol/L was a typo. Please correct as applicable.' answered with 'THE CORRECT VALUE IS 4.4mmol/L' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:40:54
Query 'Per DM CLR: SAE Narrative = Patient was diagnosed with new onset V-Fib. However, AE term is Atrial Fibrillation. Please review and reconcile data as appropriate.' answered with 'SUBJECT WAS DIAGNOSED WITH NEW ONSET A-FIB ACCORDING TO DISCHARGE SUMMARTY DATED 05SEP2020.' (Site from DM).	Albert Garcia (b) (4)	10 Nov 2020 19:38:04
Query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' answered with 'UNABLE TO CONFIRM UNTIL REQUESTED RECORDS ARE RECEIVED.' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:04:58
Query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' answered with 'DISCHARGE RECORDS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:04:28
User opened query 'PV Query: Please clarify if potassium value 0.4 mmol/L was a typo. Please correct as applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:48:34

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The case narrative section refers to V-fib. Please confirm if the subject ever had a rhythm of V-fib or update the narrative.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:48:15
User opened query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:47:33
User opened query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:47:11
User opened query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:46:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 21:25:33
User opened query 'Per DM CLR: SAE Narrative = Patient was diagnosed with new onset V-Fib. However, AE term is Atrial Fibrillation. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:47:38

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I WAS CALLED BY THE PATIENT TONIGHT 06/SEP/2020 SUBJECT WENT TO A REGULARLY SCHEDULED DOCTOR'S APPOINTMENT ON 03/SEP/2020, AND HER PHYSICIAN LISTENED TO HER BREATH SOUNDS AND THEN APICAL AND SAID YOUR HEART RATE IS TOO FAST AND SENT HER TO THE EMERGENCY ROOM. WHERE THEY DIAGNOSED HER WITH NEW ONSET OF V-FIB. SHE STAYED FROM 03/SEP/2020 AND DISCHARGED ON 05/SEP/2020. I AM REQUESTING THE DISCHARGE SUMMARY DIAGNOSED WITH ATRIAL FIBRILLATION WITH RVR, AND ESSENTIAL HYPERTENSION. SHE WAS EVALUATED BY A CARDIOLOGIS WHO PRESCRIBED HER ELIQUIS AND PRESCRIBED HER METOPROLOL WITH INSTRUCTIONS NOT TO TAKE WHEN HEART RATES IS LESS THAN 58 OR BLOOD PRESSURE IS LESS THAN 110 SYSTOLIC. SHE WAS DISCHARGED OVER TO HER DAUGHTER AND IN STABLE CONDITION.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Oct 2020 15:28:31
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:20:23
User closed query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:20:22
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:20:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

2063 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:20:18
User closed query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:20:15
Query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:43:15
Query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:42:33
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).' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:42:19
Query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:42:09
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'WE ARE AWAITING MEDICAL RECORDS' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:41:52

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 12:12:39
User opened query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 12:12:26
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).' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 12:12:17
User opened query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 12:12:07
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 12:12:00
User closed query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:17:08
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:17:07
User closed query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:17:05

PRODUCTION RELEASE (v12.003
EAB) (1725)

2065 of 2428

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:17:02
User closed query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:17:01
Query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:20:36
Query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:20:31
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).' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:20:26
Query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:20:22

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:20:17
User opened query 'PV Query: Please confirm WBC, RBC, hematocrit and platelet results provided in the discharge summary as they were illegible. Please include units and reference ranges.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 20:02:06
User opened query 'PV Query: Please confirm if the subject was in sinus rhythm at discharge. If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 20:00:16
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).' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 19:59:35
User opened query 'PV Query: Please provide any relevant laboratory (ck/mb, troponin, etc.) and diagnostic test results (EKG, echocardiogram, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 19:59:24
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 19:58:58

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User entered 'I was called by the patient tonight 06/Sep/2020 Subject went to a regularly scheduled doctor's appointment on 03/Sep/2020, and her physician listened to her breath sounds and then apical and said your heart rate is too fast and sent her to the emergency room. Where they diagnosed her with new onset of V-fib. She stayed from 03/Sep/2020 and discharged on 05/Sep/2020. I am requesting the discharge summary.'	douglas winter (b) (4) (b) (4)	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 14:58:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Sep 2020 16:56:03

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Essential hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 22:43:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 22:43:05
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 22:42:10
User entered 'ESSENTIAL HYPERTENSION'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '05 Sep 2020'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered 'Yes (Y)'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	24 Nov 2020 22:41:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 22:41:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 22:41:18
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:48:28
Query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' answered with 'LOG LINE #5. PLEASE REVIEW.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 14:05:52
User opened query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:35:33
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:34:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	09 Dec 2020 19:16:06
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. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 02:12:54
User entered 'I'	douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '0'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	douglas winter (b) (4)	24 Nov 2020 22:41:53
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4)	24 Nov 2020 22:41:18
	(b) (4)	

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'DIAGNOSIS IS SECONDARY TO THE SAE.'	(b) (4) douglas winter (b) (4) (b) (4)	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 22:41:18

US3222059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 14:58:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 22:41:18

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 14:58:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	14 Oct 2020 15:06:10
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	09 Oct 2020 15:39:50

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
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.	(b) (4) Coder Import (b) (4)	14 Nov 2020 22:02:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 22:02:52
Data point term sent to Coder	System	14 Nov 2020 13:44:23
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:43:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:14
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)	14 Oct 2020 15:26:32
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 Oct 2020 15:26:32
Data point term sent to Coder	System	14 Oct 2020 15:07:28
User entered 'ACETAMENOPHEN'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:12:24
Query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:43:49
User entered 'OSTEOARTHRITIS - KNEES - B/L' reason for change: Data Entry Error	Albert Garcia (b) (4)	14 Nov 2020 13:43:44
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:43:33
User entered 'OSTEOARTHRITIS - KNEES' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:43:33
User opened query 'Per CDM: Please update and provide location of 'OSTEOARTHRITIS' (e.g. Knees, Elbows, Hips, etc.). Please ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:12:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'OSTEOARTHRITIS'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '500'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'as needed (PRN)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '21 Sep 2000'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:13

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:09:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:09:28
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 15:08:28
User entered 'ALBUTEROL'	Albert Garcia (b) (4)	14 Oct 2020 15:07:57
	(b) (4)	

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'ALLERGIC RHINITIS'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'I'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'puff (PUFF)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'as needed (PRN)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '01 Jan 2016'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:07:57

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:10:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:10:33
Data point term sent to Coder	System	14 Oct 2020 15:09:29
User entered 'ALLEGRA'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per CDM: Please verify if this pertains to SINUSITIS in Medical History eCRF. If yes, note that Con Med start date is prior to the start date of the Med History condition (01-JAN-2011)? Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 13:00:43
Query 'Per CDM: Please verify if this pertains to SINUSITIS in Medical History eCRF. If yes, note that Con Med start date is prior to the start date of the Med History condition (01-JAN-2011)? Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'Per patient, she was diagnosed in 2009. History date updated' (Site from DM).	(b) (4), (b) (6) douglas winter (b) (4) (b) (4)	04 Nov 2020 18:47:14 30 Oct 2020 15:02:52
User opened query 'Per CDM: Please verify if this pertains to SINUSITIS in Medical History eCRF. If yes, note that Con Med start date is prior to the start date of the Med History condition (01-JAN-2011)? Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM). User entered 'SINUSITIS'	(b) (4), (b) (6) Albert Garcia (b) (4) (b) (4)	26 Oct 2020 17:17:24 14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '180'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '01 Jan 2009'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:08:39

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:11:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:11:31
Data point term sent to Coder	System	14 Oct 2020 15:10:30
User entered 'ELIQUIS'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'A-FIB'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '2.5'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'twice daily (BID)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '05 Sep 2020'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:09:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 15:22:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 15:22:08
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	09 Dec 2020 19:15:19 09 Dec 2020 19:15:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 13:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 13:44:49
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	14 Nov 2020 13:44:25 14 Nov 2020 13:44:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:00:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 17:00:36
Data point term sent to Coder User entered 'METOPROLOL'	System Albert Garcia (b) (4)	14 Oct 2020 15:11:32 14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
DataPoint Un-verified.	Albert Garcia (b) (4)	09 Dec 2020 19:15:18
	(b) (4)	
User entered 'A-FIB/ESSENTIAL HTN' reason for change: Data Entry Error	Albert Garcia (b) (4)	09 Dec 2020 19:15:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'A-FIB'	Albert Garcia (b) (4)	14 Oct 2020 15:10:34
	(b) (4)	

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '25'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:14:03
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:44:17
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:44:13
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:44:13
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 10:45:05
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Topical (TOPICAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '05 Sep 2020'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 16:16:37
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' answered with 'WE HAVE NOT BEEN PROVIDED AN UPDATE AS FAR AS REOLUTION. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 14:36:06
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:16:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:10:34

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:12:34
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 Oct 2020 17:12:34
Data point term sent to Coder	System	14 Oct 2020 15:11:32
User entered 'DILTIAZAM'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'A-FIB'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '180'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '05 Sep 2020'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:11:03

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:47:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:36:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:36:58
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: OMEPRAZOLE, PRODUCTSYNONYM: PROTONIX [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:13:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:13:40
Data point term sent to Coder	System	14 Oct 2020 15:12:35
User entered 'PROTONIX'	Albert Garcia (b) (4)	14 Oct 2020 15:11:45
	(b) (4)	

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'GERD'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '40'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '01 Jan 2010'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered '0'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered empty.	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:14
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 14:58:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:11:45

US3222059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 14:58:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:52
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	09 Oct 2020 15:40:08

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
User entered '16/Sep/2020 08:41'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
User entered '13/Oct/2020 09:53'	System	13 Oct 2020 13:53:12

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:09:27
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 13:53:12

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
User entered '02/Nov/2020 17:10'	System	02 Nov 2020 17:10:48

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:12:21
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 17:10:48

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 14:14:24
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 14:13:52

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
Un-reviewed for Safety.	(b) (4)	
	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'USA-US104-2020-MRNA-1273-P301000001'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '11/Nov/2020 14:14'	(b) (4) System	11 Nov 2020 14:14:47

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 15:43:57
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 14:14:47

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '19/Nov/2020 15:44'	(b) (4) System	19 Nov 2020 15:44:11

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:07
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 15:44:11

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '25/Nov/2020 11:33'	(b) (4) System	25 Nov 2020 16:33:36

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:44:22
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 16:33:36

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
Un-reviewed for Safety.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '03/Dec/2020 10:44'	(b) (4) System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
Un-reviewed for Safety.	(b) (4)	
	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '07/Dec/2020 08:18'	(b) (4) System	07 Dec 2020 13:18:10

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 13:18:10

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:44:22
Comment added 'SITE AND INVESTIGATOR ARE INCORRECT ON THIS PAGE. PLEASE REVIEW AND CORRECT.'.	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
Un-reviewed for Safety.	(b) (4)	
	Albert Garcia (b) (4)	02 Dec 2020 13:28:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered	System	16 Sep 2020 12:41:01
'USA-US104-2020-MRNA-1273-P301000001'		

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Yes (Y)'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'No (N)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Yes (Y)'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Teresa'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Lisa'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Tracy'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Vicki'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered 'Becker'	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
User entered 'Holloway'	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:10
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered 'Kowalski'	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Miller'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '6550 mapleridge,'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered 'Houston'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered 'Houston'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Un-reviewed for Safety.	System	11 Dec 2020 21:18:16
User entered empty.	System	11 Dec 2020 21:18:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
User entered 'TX'	System	03 Dec 2020 15:44:37

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 21:17:55
Un-reviewed for Safety.	System	03 Dec 2020 15:44:37
DataPoint Un-verified.	System	03 Dec 2020 15:44:37
User entered '77081'	System	03 Dec 2020 15:44:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Un-reviewed for Safety.	System	12 Oct 2020 15:18:50
User entered empty.	System	12 Oct 2020 15:18:50
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 12:41:24
User entered '77081'	System	16 Sep 2020 12:41:01

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:54:04
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:17:22
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:39:38
User entered 'US' (non-conformant).	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Jun 2021 14:58:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
	(b) (4)	
User entered '9'	System	11 Dec 2020 21:18:16
User entered '8'	System	07 Dec 2020 13:18:10
User entered '7'	System	03 Dec 2020 15:44:37
User entered '6'	System	25 Nov 2020 16:33:36
User entered '5'	System	19 Nov 2020 15:44:11
User entered '4'	System	11 Nov 2020 14:14:47
User entered '3'	System	02 Nov 2020 17:10:48
User entered '2'	System	13 Oct 2020 13:53:12
User entered '1'	System	16 Sep 2020 12:41:31

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 11 Jun 2021 14:58:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered '11/Dec/2020 16:18'	(b) (4) System	11 Dec 2020 21:18:16

US3222059

Folder: SAE USA-US104-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 11 Jun 2021 14:58:14

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.	Bruce Rankin (b) (4)	19 Feb 2021 15:08:47
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 21:18:16