

US3202197 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:42:37

All time stamps listed in this document are displayed in GMT

US3202197

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

[Participant ID](#)

US3202197

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

US3202197

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

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

Visit date (dd MMM yyyy)	15 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3202197

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	73
Age Units	YEARS
Age (Derived)	74
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input checked="" type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:11:34

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Date of Informed Consent (<i>dd MMM yyyy</i>)	15 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:11:35

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	PLACEMENT OF CARDIAC PACEMAKER
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

US3202197

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	KIDNEY DISEASE- CAUSED BY ALLERGIC REACTION TO STATINS
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	ALLERGIC TO STATINS- CAUSED KIDNEY DISEASE
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	CHRONIC HIP PAIN BILATERAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	ABDOMINAL AORTIC ANEURYSM
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	GENERAL GOUT
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 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)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	RIGHT CAROTID ARTERY STENOSIS
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 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)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Condition	LEFT CAROTID ARTERY STENOSIS
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 AUG 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 08:49
Height (xxx.x)	179.0 cm
Weight (xxx.x)	122.2 kg
BMI (xxx.x)	38.13863 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:35

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:35

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

What was the date of randomization? (dd MMM yyyy) 15 AUG 2020

What was the participant's randomization number? 186328

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

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)	15 AUG 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 08:49
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 AUG 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	15 AUG 2020 10:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 15 AUG 2020

What was the treatment time? (00:00-23:59) 09:31 (24 HR)

Treatment Date and Time (derived) 15 AUG 2020 09:31

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 AUG 2020
Collection time (00:00-23:59)	08:56 (24 HR)
Collection date and time (derived)	15 AUG 2020 08:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Collection date (dd MMM yyyy)			15 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:54	15 AUG 2020 08:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 10:11

PC Open Date & Time

15 AUG 2020 09:51

PC Close Date & Time

15 AUG 2020 12:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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 15 AUG 2020 13:16

PC Close Date & Time 16 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

17 AUG 2020 12:23

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

18 AUG 2020 14:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

19 AUG 2020 12:09

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 12:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

15 AUG 2020 10:12

PC Open Date & Time

15 AUG 2020 09:51

PC Close Date & Time

15 AUG 2020 12:21

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

15 AUG 2020 13:16

PC Close Date & Time

16 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:42

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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 AUG 2020 12:24

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 14:44

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:10

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 12:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 10:13
PC Open Date & Time	15 AUG 2020 09:51
PC Close Date & Time	15 AUG 2020 12:21

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 13:16

PC Close Date & Time

16 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:43
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:25
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 14:46
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:02
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:05
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3202197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments NO ANSWER

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 SEP 2020

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

Comments NO ANSWER

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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)	14:12 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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)	15:46 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 15:46
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3202197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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.

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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) 15:06 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 15:06

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

What was the frequency of the study treatment dosing? ONCE

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

US3202197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

14 SEP 2020 14:30

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

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	14:28	14 SEP 2020 14:28
Nasopharyngeal Swab 2	No		

US3202197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:35

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:24

PC Open Date & Time

14 SEP 2020 15:26

PC Close Date & Time

14 SEP 2020 17:56

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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 98.3 °F

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

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

PC Time Stamp	14 SEP 2020 19:29
PC Open Date & Time	14 SEP 2020 18:51
PC Close Date & Time	15 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

97.8 °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

16 SEP 2020 21:39

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:10

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

20 SEP 2020 22:41

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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 16:25

PC Open Date & Time

14 SEP 2020 15:26

PC Close Date & Time

14 SEP 2020 17:56

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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 19:30

PC Open Date & Time

14 SEP 2020 18:51

PC Close Date & Time

15 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 12:03

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:40

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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 12:05

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:10

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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 22:42

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 16:26
PC Open Date & Time	14 SEP 2020 15:26
PC Close Date & Time	14 SEP 2020 17:56

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 19:30
PC Open Date & Time	14 SEP 2020 18:51
PC Close Date & Time	15 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:04
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:41
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 12:08
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

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 ☒

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:42
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:14 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 13:14
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

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.

US3202197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

13:22 (24 HR)

Collection date and time (derived)

12 OCT 2020 13:22

US3202197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:36

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 21:27:18

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

23 OCT 2020 09:15:48

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 11:54:57

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

12 NOV 2020 20:57:32

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 19:58:15
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 22:30:15

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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	30 NOV 2020 18:19:59
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

07 DEC 2020 16:49:52

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

16 DEC 2020 17:05:14

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

21 DEC 2020 22:39:03

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 22:48:18

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

04 JAN 2021 17:43:14

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

11 JAN 2021 09:59:45

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 23:31:45

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

02 FEB 2021 12:43:11

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

08 FEB 2021 20:54:32

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 20:03:36

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 194

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 12:17:26

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 19:21:04

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

15 MAR 2021 12:14:42

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

24 MAR 2021 19:30:55

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 19:44:01

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 20:48:23

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

26 APR 2021 13:56:41

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 <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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2021 00:01
Patient Cloud Close Date & Time	23 JUL 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 AUG 2021 00:01
Patient Cloud Close Date & Time	27 AUG 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Patient Cloud Open Date & Time	20 SEP 2021 00:01
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Patient Cloud Close Date & Time	24 SEP 2021 23:59
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US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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="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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Patient Cloud Open Date & Time	25 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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="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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Patient Cloud Open Date & Time	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 NOV 2021 00:01
Patient Cloud Close Date & Time	26 NOV 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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°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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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°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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 MAR 2022 00:01
Patient Cloud Close Date & Time	18 MAR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 APR 2022 00:01
Patient Cloud Close Date & Time	15 APR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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°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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2022 00:01
Patient Cloud Close Date & Time	01 JUL 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 740

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2022 00:01
Patient Cloud Close Date & Time	23 SEP 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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 ☐

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Patient Cloud Open Date & Time	10 OCT 2022 00:01
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Patient Cloud Close Date & Time	14 OCT 2022 23:59
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US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3202197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:42:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 12:17:38

US3202197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:45:11

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

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

Visit date (dd MMM yyyy)	11 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
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US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

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) _____

US3202197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

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.

US3202197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	12:58 (24 HR)
Collection date and time (derived)	11 MAR 2021 12:58

US3202197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:20:17

Generated On: 09 Jun 2021 15:42:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202197

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:20:17

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202197

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202197

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:42:37

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

US3202197

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:42:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202197

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

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

Visit date (dd MMM yyyy)	11 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
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US3202197

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

Date of updated informed consent (dd MMM yyyy) 11 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3202197

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	11 JAN 2021 11:34

US3202197

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	11:29
Collection Date and Time (derived)	11 JAN 2021 11:29

US3202197

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

AEID	USA-US128-2021-MRNA-1273-P30 1000015
Adverse event	RIGHT CAROTID STENOSIS
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)	21 OCT 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)	21 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

SUBJECT HAD
ENDARTERECTOMY DUE TO
MEDICAL
HISTORY--CONDITION NOT
WORSENING SO UNCLEAR
HOW TO REPORT AS AN AE,
BUT PROCEDURE TO TREAT
CONDITION REQUIRED
OVERNIGHT HOSPITALIZATION
(<24 HOURS) THUS REPORTED
AS SAE PER PROTOCOL
GUIDELINES FOR
HOSPITALIZATIONS. NO LABS
INCLUDED IN RECORDS OTHER
THAN PATHOLOGY ON THE
PLAQUE REMOVED AND NO
MALIGNANCY NOTED. NO
COVID-19 TESTS NOTED,
DIAGNOSTIC SUMMARY IN
OPERATIVE REPORT MENTIONS
THAT RIGHT CAROTID WAS
WORSE (PATIENT REPORTED
100% OCCLUDED) PER ECHO
AND CAROTID ULTRASOUND
DONE IN JUNE 2020

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

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

AEID	USA-US128-2021-MRNA-1273-P30 1000017
Adverse event	LEFT CAROTID STENOSIS
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)	19 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	19 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

SUBJECT HAD
ENDARTERECTOMY DUE TO
MEDICAL
HISTORY--CONDITION NOT
WORSENING SO UNCLEAR
HOW TO REPORT AS AN AE,
BUT PROCEDURE TO TREAT
CONDITION REQUIRED
OVERNIGHT HOSPITALIZATION
(<24 HOURS) THUS REPORTED
AS SAE PER PROTOCOL
GUIDELINES FOR
HOSPITALIZATIONS.

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

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Apr 2021 17:57:33

Generated On: 09 Jun 2021 15:42:37

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

Yes ☒

No ☐

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

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUTY ARTHRITIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication TERAZOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication PANTOPRAZOLE NA

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<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"/>

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication PRALUENT

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 2 WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	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)		08 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication RIGHT CAROTID
ENDARTERECTOMY
PROCEDURAL PROPHYLAXIS

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication GENERAL ENDOTRACHEAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication RIGHT CAROTID STENOSIS

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication LEFT CAROTID
ENDARTERECTOMY
PROCEDURAL PROPHYLAXIS

Dose per administration 4000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

Name of Medication GENERAL ENDOTRACHEAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication LEFT CAROTID STENOSIS
(PROCEDURAL ANESTHESIA
FOR LEFT CAROTID
ENDARTERECTOMY)

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:36:33

Generated On: 09 Jun 2021 15:42:37

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:36:34

Generated On: 09 Jun 2021 15:42:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 OCT 2020	RIGHT CAROTID ENDARTARECTOMY WITH BOVINE PATCH ANGIOPLASTY	Medical History	
19 JAN 2021	LEFT CAROTID ENDARTERECTOMY WITH BOVINE PATCH ANGIOPLASTY	Medical History	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:42:37

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 ☐

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Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 13:42:44

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 13:42:44

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 13:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 13:42:44

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 11:29
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

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Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 13:42:44

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 06:18
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

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:34:27

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:34:27

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 12:32
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

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:34:27

Generated On: 09 Jun 2021 15:42:37

SAEID	USA-US128-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 07:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202197 (Prod: WR-ClinSearch, LLC)

US3202197

Form: Participant Creation

Generated On: 09 Jun 2021 15:42:37

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:41:49
User entered 'US3202197'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:34:16

US3202197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:26

US3202197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:34:17

US3202197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:26

US3202197

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'SCRN'	System	15 Aug 2020 13:07:26

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:34:17

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '73'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'YEARS'	System	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '74'	System	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Male (M)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Not Reported (NOT REPORTED)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'I'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:42:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:32:28

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Aug 2020'	System	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2020'	System	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:07:45

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:34:17

US3202197

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:42:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'I'	System	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:42:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:33:52

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:25:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 15:25:39
Data point term sent to Coder	System	24 Aug 2020 13:34:35
User entered 'Sleep apnea- Uses a C-pap'	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2000'	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2000'	System	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2000'	System	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:34:24

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:36:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:36:38
Data point term sent to Coder	System	24 Aug 2020 13:35:38
User entered 'Hypothyroidism'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2001'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2001'	System	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2001'	System	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:35:17

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
Query 'Per CDM: Please note that there is no Con Med that matches this MH condition? Please ensure that there is a corresponding Con Med/AE record that match the updated condition. Please update applicable details as appropriate or, provide further clarification.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 10:07:03
User opened query 'Per CDM: Please note that there is no Con Med that matches this MH condition? Please ensure that there is a corresponding Con Med/AE record that match the updated condition. Please update applicable details as appropriate or, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:05:16
User closed query 'Per DM CLR: Please update MH term to reflect the heart disease name, if known. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:04:28
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 01:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 01:59:43
Data point term sent to Coder	System	19 Sep 2020 01:58:45
User entered 'CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 01:58:15
Query 'Per DM CLR: Please update MH term to reflect the heart disease name, if known. Please reconcile with the Con Med eCRF as necessary.' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 01:57:55
Data point term sent to Coder	System	19 Sep 2020 01:57:44
Coding entries removed.	Erica Osmundsen (b) (4)	19 Sep 2020 01:57:43
User entered 'AORONARY ARTERY DISEASE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 01:57:43

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update MH term to reflect the heart disease name, if known. Please reconcile with the Con Med eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:49:23
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac disorders NEC, PT: Cardiac disorder, LLT: Heart disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:37:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:37:43
Data point term sent to Coder	System	24 Aug 2020 13:36:39
User entered 'Heart Disease'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2014'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2014'	System	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2014'	System	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:35:52

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:50:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:50:01
Data point term sent to Coder	System	19 Sep 2020 01:59:46
Coding entries removed.	Erica Osmundsen (b) (4)	19 Sep 2020 01:58:55
User entered 'PLACEMENT OF CARDIAC PACEMAKER' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 01:58:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 05:32:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 05:32:50
Data point term sent to Coder	System	24 Aug 2020 13:44:59
Coding entries removed.	Tiffany Jewell (b) (4)	24 Aug 2020 13:44:11
User entered 'PACEMAKER- 3 wire' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	24 Aug 2020 13:44:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac pacemaker insertion, LLT: Cardiac pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:37:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:37:43
Data point term sent to Coder	System	24 Aug 2020 13:36:39
User entered 'Pacemaker'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2014'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Oct 2020 09:05:46
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 01:59:33
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 01:59:18
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:49:39
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2014' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 01:59:18
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2014'	System	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2014'	System	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2014'	System	19 Sep 2020 01:59:18
User entered empty.	System	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2014'	System	19 Sep 2020 01:59:18
User entered empty.	System	24 Aug 2020 13:36:08

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Defibrillator/pacemaker insertion - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:51:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:51:05
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:06:59
Data point term sent to Coder	System	19 Sep 2020 02:00:46
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:00:30
Coding entries removed.	Erica Osmundsen (b) (4)	19 Sep 2020 02:00:18
User entered 'PLACEMENT OF CARDIAC PACEMAKER DEFIBRILLATOR' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:00:18
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:50:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Defibrillator/pacemaker insertion - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 15:41:41

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 13:45:00
User entered 'Pacemaker DEFIBRILLATOR' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	24 Aug 2020 13:44:51
Data point term sent to Coder	(b) (4)	24 Aug 2020 13:37:41
User entered 'Defibrillator'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:49
	(b) (4)	

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Tiffany Jewell (b) (4)	24 Aug 2020 13:44:51
User entered 'UN UNK 2020'	(b) (4)	
	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:49
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Oct 2020 09:06:05
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:00:41
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:00:18
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:49:57
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:00:18
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2015'	System	24 Aug 2020 13:44:51
User entered 'Jan 2020'	System	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2015'	System	24 Aug 2020 13:44:51
User entered '2020'	System	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2015'	System	19 Sep 2020 02:00:18
User entered empty.	System	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2015'	System	19 Sep 2020 02:00:18
User entered empty.	System	24 Aug 2020 13:36:49

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Renal and urinary disorders, HLGT: Nephropathies, HLT: Nephropathies and tubular disorders NEC, PT: Nephropathy toxic, LLT: Drug-induced renal disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:58:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 21:58:50
Data point term sent to Coder	System	24 Aug 2020 13:37:41
User entered 'Kidney Disease- caused by allergic reaction to statins'	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2011'	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2011'	System	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2011'	System	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:37:36

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 08:57:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 08:57:47
Data point term sent to Coder	System	24 Aug 2020 13:38:42
User entered 'Allergic to Statins- Caused kidney disease'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2011'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2011'	System	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2011'	System	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:04

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 07:30:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 07:30:35
Data point term sent to Coder	System	14 Sep 2020 21:50:02
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	14 Sep 2020 21:49:38
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'DONE' (Site from System).	Erica Osmundsen (b) (4)	14 Sep 2020 21:49:38
User entered 'CHRONIC HIP PAIN BILATERAL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Sep 2020 21:49:32
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	31 Aug 2020 14:27:28
Data point term sent to Coder	System	24 Aug 2020 13:38:42
User entered 'Chronic hip and back pain'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'I'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:38:30

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:36:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:36:43
Data point term sent to Coder	System	24 Aug 2020 13:39:44
User entered 'Heartburn/Acid reflux'	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2000'	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2000'	System	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2000'	System	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:39:04

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Abdominal aortic aneurysm - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:42:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 13:42:45
Data point term sent to Coder	System	24 Aug 2020 13:41:48
User entered 'Abdominal Aortic Aneurysm'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2014'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2014'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2014'	System	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2014'	System	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2014'	System	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2014'	System	24 Aug 2020 13:41:44

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per DM CLR RQ: Response noted. Please review if term should be updated as 'General Gout Arthritis' to reflect location per response. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:35:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:19:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 22:19:37
Data point term sent to Coder	System	29 Sep 2020 20:13:20
Query 'Per DM CLR RQ: Response noted. Please review if term should be updated as 'General Gout Arthritis' to reflect location per response. ' answered with 'QUERY CORRECTED' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 20:12:47
User entered 'GENERAL GOUT' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 20:12:28
Data point term sent to Coder	System	29 Sep 2020 20:12:19
Coding entries removed.	(b) (4), (b) (6)	29 Sep 2020 20:11:54
User entered 'GOUT' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 20:11:54
User opened query 'Per DM CLR RQ: Response noted. Please review if term should be updated as 'General Gout Arthritis' to reflect location per response. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:31:22
User closed query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:31:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Crystal arthropathic disorders, PT: Gouty arthritis, LLT: Gouty arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 02:03:44

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'GOUT FLARES AT DIFFERENT JOINTS OVER COURSE OF ILLNESS' (Site from DM).	Coder Import (b) (4)	19 Sep 2020 02:03:44
Data point term sent to Coder Coding entries removed.	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:03:13
User entered 'GOUTY ARTHRITIS' reason for change: Data Entry Error	System Erica Osmundsen (b) (4)	19 Sep 2020 02:02:48 19 Sep 2020 02:02:43
User opened query 'Per DM CLR: Please specify the location and/or type of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:54:07
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:45:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:45:41
Data point term sent to Coder	System	24 Aug 2020 13:43:58
User entered 'Gout'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2005'	Tiffany Jewell (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2005'	System	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2005'	System	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	24 Aug 2020 13:43:20

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 21:50:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 21:50:52
Data point term sent to Coder	System	14 Sep 2020 21:50:01
User entered 'CHRONIC BACK PAIN'	Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	14 Sep 2020 21:49:48

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:08:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:08:46
Data point term sent to Coder	System	19 Sep 2020 02:07:51
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 1995'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 1995'	System	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '1995'	System	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	19 Sep 2020 02:06:59

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Sep 2020 02:10:46
Data point term sent to Coder	System	19 Sep 2020 02:09:52
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN UNK 2010'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2010'	System	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2010'	System	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	19 Sep 2020 02:09:11

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:33:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 16:33:48
Data point term sent to Coder	System	12 Feb 2021 16:33:27
User entered 'right carotid artery stenosis'	Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'UN Jun 2020'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	(b) (4) Teresa Deese (b) (4)	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jun 2020'	System	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2020'	System	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	12 Feb 2021 16:32:48

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Feb 2021 16:06:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Feb 2021 16:06:08
Data point term sent to Coder	System	21 Feb 2021 16:04:45
User entered 'Hyperlipidemia'	zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'un UNK 2010'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered '0'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered empty.	(b) (4) zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered '0'	(b) (4) zackery harmon (b) (4)	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2010'	System	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2010'	System	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	21 Feb 2021 16:04:07

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 21:50:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 21:50:53
Data point term sent to Coder	System	11 Mar 2021 21:35:27
User entered 'LEFT CAROTID ARTERY STENOSIS'	Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'UN Jan 2020'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered 'Jan 2020'	System	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered '2020'	System	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User entered empty.	System	11 Mar 2021 21:34:53

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '08:49'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User entered '15 Aug 2020 08:49'	System	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '179.0' cm	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48
DataPoint set to visible.	(b) (4) System	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '122.2' kg	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48
DataPoint set to visible.	(b) (4) System	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
Amendment Manager: User entered '38.13863'	System	16 Sep 2020 23:58:19
User entered '38.1'	System	24 Aug 2020 14:12:48
DataPoint set to visible.	System	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User entered 'kg/m2'	System	24 Aug 2020 14:12:48
DataPoint set to visible.	System	15 Aug 2020 13:07:52

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:15:36
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 20:15:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Dec 2020 20:15:10
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:02:30
User entered 'Other (Other)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic is recorded as Not Done, please remove beats/min, breaths/min, or mmHg.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 09:07:42
Query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic is recorded as Not Done, please remove beats/min, breaths/min, or mmHg.' answered with 'cannot remove from this end. please send request to your IT dept' (Site from DM).	Teresa Deese (b) (4)	14 Jan 2021 18:44:59
User opened query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic is recorded as Not Done, please remove beats/min, breaths/min, or mmHg.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 17:58:56
User entered missing code ND - Not Done.	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
Query ' Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 14:59:07
User opened query ' Per CDM: Please remove data from this field, this should be blank if Pulse is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 17:59:18
User entered 'bpm'	System	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
Query ' Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 14:59:08
User opened query ' Per CDM: Please remove data from this field, this should be blank if Respiratory Rate is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 17:59:32
User entered 'breaths/min'	System	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
Query ' Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 14:59:10
User opened query ' Per CDM: Please remove data from this field, this should be blank if Systolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 17:59:59
User entered 'mmHg'	System	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered missing code ND - Not Done.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
Query ' Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' canceled (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 14:59:11
User opened query ' Per CDM: Please remove data from this field, this should be blank if Diastolic Blood Pressure is Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 18:00:38
User entered 'mmHg'	System	24 Aug 2020 14:12:48

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 18:13:33

US3202197

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33

US3202197

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:12:53

US3202197

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:12:53

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'I'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:42:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:36:07
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:13:37

US3202197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:02

US3202197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:02

US3202197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:08:02

US3202197

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'VISIT1'	System	15 Aug 2020 13:08:02

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:49:26

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:45:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:45:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Aug 2020 12:49:26
User entered '186328' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:49:26

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Aug 2020 12:49:26

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:07:22
Query ' PER CDM: Please complete this section of the form' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	03 Sep 2020 12:03:49
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	03 Sep 2020 12:03:42
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:25:46

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 12:03:42

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 12:03:42

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 12:03:42

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 12:03:42

US3202197

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:42:37

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 20:40:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:26:58

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:01
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:41
User entered '179.0' cm	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:03
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:45
User entered '122.2' kg	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:01
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:41
User entered '179.0' cm	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:03
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:45
User entered '122.2' kg	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '08:49'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '15 Aug 2020 08:49'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '37.1' C	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '68'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'bpm'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '20'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'breaths/min'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '130'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '81'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:01
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:41
User entered '179.0' cm	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:42:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:09:03
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	28 Sep 2020 01:34:11
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please remove data and update with "ND" ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:02:45
User entered '122.2' kg	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '10:16'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '15 Aug 2020 10:16'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '36.6' C	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '77'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'bpm'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '20'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'breaths/min'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '123'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '79'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	24 Aug 2020 14:17:13

US3202197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:21

US3202197

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Aug 2020 14:17:21

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'MRNA-1273 OR PLACEBO'	System	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '09:31'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '15 Aug 2020 09:31'	System	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'ONCE'	System	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'INTRAMUSCULAR'	System	15 Aug 2020 13:55:22

US3202197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:20

US3202197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:20

US3202197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '08:56'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:08:20

US3202197

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '15 Aug 2020 08:56'	System	15 Aug 2020 13:08:20

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15 Aug 2020'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '08:54'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '15 Aug 2020 08:54'	System	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered empty.	System	15 Aug 2020 13:08:35

US3202197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:09:59

US3202197

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	21 Aug 2020 21:09:59

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:11:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f305ebb9-7b77-4447-8772-0f61029ec865'	System	15 Aug 2020 14:11:50
User entered 'Yes (Y)'	System	15 Aug 2020 14:11:50

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:11:30', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f305ebb9-7b77-4447-8772-0f61029ec865' User entered '97.8'	System	15 Aug 2020 14:11:50
	System	15 Aug 2020 14:11:50

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:11:38', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f305ebb9-7b77-4447-8772-0f61029ec865'	System	15 Aug 2020 14:11:50
User entered 'No (N)'	System	15 Aug 2020 14:11:50

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:11:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f305ebb9-7b77-4447-8772-0f61029ec865'	System	15 Aug 2020 14:11:50
User entered '15 Aug 2020 10:11'	System	15 Aug 2020 14:11:50

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 09:51'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 12:21'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 13:16'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 2'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:41:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e1eee026-4bc8-4450-a7af-2ad5d2d3f3ff' User entered 'Yes (Y)'	System	17 Aug 2020 00:41:58
	System	17 Aug 2020 00:41:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:41:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e1eee026-4bc8-4450-a7af-2ad5d2d3f3ff' User entered '98.7'	System	17 Aug 2020 00:41:58
	System	17 Aug 2020 00:41:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:41:47', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e1eee026-4bc8-4450-a7af-2ad5d2d3f3ff'	System	17 Aug 2020 00:41:58
User entered 'No (N)'	System	17 Aug 2020 00:41:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:41:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e1eee026-4bc8-4450-a7af-2ad5d2d3f3ff' User entered '16 Aug 2020 20:41'	System	17 Aug 2020 00:41:58
	System	17 Aug 2020 00:41:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 3'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:22:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b054c32-5351-419e-9084-0b81f6e0b7f7'	System	17 Aug 2020 16:23:33
User entered 'Yes (Y)'	System	17 Aug 2020 16:23:33

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b054c32-5351-419e-9084-0b81f6e0b7f7' User entered '97.7'	System	17 Aug 2020 16:23:33
	System	17 Aug 2020 16:23:33

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:16', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b054c32-5351-419e-9084-0b81f6e0b7f7'	System	17 Aug 2020 16:23:33
User entered 'No (N)'	System	17 Aug 2020 16:23:33

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b054c32-5351-419e-9084-0b81f6e0b7f7'	System	17 Aug 2020 16:23:33
User entered '17 Aug 2020 12:23'	System	17 Aug 2020 16:23:33

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 4'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '746a4129-d8c1-4303-a0f3-0c5acafac928'	System	18 Aug 2020 18:44:30
User entered 'Yes (Y)'	System	18 Aug 2020 18:44:30

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '746a4129-d8c1-4303-a0f3-0c5acafac928'	System	18 Aug 2020 18:44:30
User entered '98.6'	System	18 Aug 2020 18:44:30

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '746a4129-d8c1-4303-a0f3-0c5acafac928'	System	18 Aug 2020 18:44:30
User entered 'No (N)'	System	18 Aug 2020 18:44:30

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '746a4129-d8c1-4303-a0f3-0c5acafac928'	System	18 Aug 2020 18:44:30
User entered '18 Aug 2020 14:44'	System	18 Aug 2020 18:44:30

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 5'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:09:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'c8e2acd1-c1f3-485c-b781-e51bd89cf75c' User entered 'Yes (Y)'	System	19 Aug 2020 16:09:58
	System	19 Aug 2020 16:09:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:09:42', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'c8e2acd1-c1f3-485c-b781-e51bd89cf75c' User entered '97.8'	System	19 Aug 2020 16:09:58
	System	19 Aug 2020 16:09:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:09:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'c8e2acd1-c1f3-485c-b781-e51bd89cf75c'	System	19 Aug 2020 16:09:58
User entered 'No (N)'	System	19 Aug 2020 16:09:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:09:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'c8e2acd1-c1f3-485c-b781-e51bd89cf75c'	System	19 Aug 2020 16:09:58
User entered '19 Aug 2020 12:09'	System	19 Aug 2020 16:09:58

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 6'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:00:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b4ece527-86e6-4c08-9e98-c6758c3f1ad4'	System	20 Aug 2020 16:02:01
User entered 'Yes (Y)'	System	20 Aug 2020 16:02:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:02', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b4ece527-86e6-4c08-9e98-c6758c3f1ad4' User entered '98.7'	System	20 Aug 2020 16:02:01
	System	20 Aug 2020 16:02:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b4ece527-86e6-4c08-9e98-c6758c3f1ad4'	System	20 Aug 2020 16:02:01
User entered 'No (N)'	System	20 Aug 2020 16:02:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:15', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b4ece527-86e6-4c08-9e98-c6758c3f1ad4'	System	20 Aug 2020 16:02:01
User entered '20 Aug 2020 12:01'	System	20 Aug 2020 16:02:01

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 7'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:03:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '55d5e555-c6b8-4230-a9d3-2c7072d1b48d' User entered 'Yes (Y)'	System	21 Aug 2020 16:04:00
	System	21 Aug 2020 16:04:00

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:03:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '55d5e555-c6b8-4230-a9d3-2c7072d1b48d' User entered '97.6'	System	21 Aug 2020 16:04:00
	System	21 Aug 2020 16:04:00

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:03:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '55d5e555-c6b8-4230-a9d3-2c7072d1b48d'	System	21 Aug 2020 16:04:00
User entered 'No (N)'	System	21 Aug 2020 16:04:00

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:03:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '55d5e555-c6b8-4230-a9d3-2c7072d1b48d' User entered '21 Aug 2020 12:03'	System	21 Aug 2020 16:04:00
	System	21 Aug 2020 16:04:00

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1f66a315-09bb-42fa-a586-94df59320186'	System	15 Aug 2020 14:12:37
User entered 'None (1)'	System	15 Aug 2020 14:12:37

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1f66a315-09bb-42fa-a586-94df59320186'	System	15 Aug 2020 14:12:37
User entered 'No (N)'	System	15 Aug 2020 14:12:37

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1f66a315-09bb-42fa-a586-94df59320186'	System	15 Aug 2020 14:12:37
User entered 'No (N)'	System	15 Aug 2020 14:12:37

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1f66a315-09bb-42fa-a586-94df59320186'	System	15 Aug 2020 14:12:37
User entered 'None (1)'	System	15 Aug 2020 14:12:37

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1f66a315-09bb-42fa-a586-94df59320186'	System	15 Aug 2020 14:12:37
User entered '15 Aug 2020 10:12'	System	15 Aug 2020 14:12:37

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 09:51'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 12:21'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 13:16'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 2'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:12', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2c33d556-e162-41b2-8fa6-f11d57fbedba'	System	17 Aug 2020 00:42:40
User entered 'None (1)'	System	17 Aug 2020 00:42:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2c33d556-e162-41b2-8fa6-f11d57fbedba'	System	17 Aug 2020 00:42:40
User entered 'No (N)'	System	17 Aug 2020 00:42:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:21', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2c33d556-e162-41b2-8fa6-f11d57fbedba'	System	17 Aug 2020 00:42:40
User entered 'No (N)'	System	17 Aug 2020 00:42:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2c33d556-e162-41b2-8fa6-f11d57fbedba'	System	17 Aug 2020 00:42:40
User entered 'None (1)'	System	17 Aug 2020 00:42:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:38', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2c33d556-e162-41b2-8fa6-f11d57fbedba' User entered '16 Aug 2020 20:42'	System	17 Aug 2020 00:42:40
	System	17 Aug 2020 00:42:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 3'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '70cb0525-0e3f-4f3c-afb5-82213734426b'	System	17 Aug 2020 16:24:05
User entered 'None (1)'	System	17 Aug 2020 16:24:05

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:36', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '70cb0525-0e3f-4f3c-afb5-82213734426b'	System	17 Aug 2020 16:24:05
User entered 'No (N)'	System	17 Aug 2020 16:24:05

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '70cb0525-0e3f-4f3c-afb5-82213734426b' User entered 'No (N)'	System	17 Aug 2020 16:24:05
	System	17 Aug 2020 16:24:05

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:23:53', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '70cb0525-0e3f-4f3c-afb5-82213734426b'	System	17 Aug 2020 16:24:05
User entered 'None (1)'	System	17 Aug 2020 16:24:05

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '70cb0525-0e3f-4f3c-afb5-82213734426b' User entered '17 Aug 2020 12:24'	System	17 Aug 2020 16:24:05
	System	17 Aug 2020 16:24:05

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 4'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:38', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bf2c6c18-2afc-4d22-b2ed-3d283bb51caf'	System	18 Aug 2020 18:44:57
User entered 'None (1)'	System	18 Aug 2020 18:44:57

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bf2c6c18-2afc-4d22-b2ed-3d283bb51caf' User entered 'No (N)'	System	18 Aug 2020 18:44:57
	System	18 Aug 2020 18:44:57

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:46', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bf2c6c18-2afc-4d22-b2ed-3d283bb51caf' User entered 'No (N)'	System	18 Aug 2020 18:44:57
	System	18 Aug 2020 18:44:57

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bf2c6c18-2afc-4d22-b2ed-3d283bb51caf'	System	18 Aug 2020 18:44:57
User entered 'None (1)'	System	18 Aug 2020 18:44:57

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:44:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bf2c6c18-2afc-4d22-b2ed-3d283bb51caf' User entered '18 Aug 2020 14:44'	System	18 Aug 2020 18:44:57
	System	18 Aug 2020 18:44:57

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 5'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b448688f-7b99-4602-a49f-db563c28dc6e'	System	19 Aug 2020 16:10:44
User entered 'None (1)'	System	19 Aug 2020 16:10:44

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:21', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b448688f-7b99-4602-a49f-db563c28dc6e'	System	19 Aug 2020 16:10:44
User entered 'No (N)'	System	19 Aug 2020 16:10:44

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b448688f-7b99-4602-a49f-db563c28dc6e'	System	19 Aug 2020 16:10:44
User entered 'No (N)'	System	19 Aug 2020 16:10:44

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b448688f-7b99-4602-a49f-db563c28dc6e'	System	19 Aug 2020 16:10:44
User entered 'None (1)'	System	19 Aug 2020 16:10:44

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:42', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b448688f-7b99-4602-a49f-db563c28dc6e'	System	19 Aug 2020 16:10:44
User entered '19 Aug 2020 12:10'	System	19 Aug 2020 16:10:44

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 6'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '554d2150-f939-4f85-9882-09e922992762'	System	20 Aug 2020 16:02:40
User entered 'None (1)'	System	20 Aug 2020 16:02:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:29', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '554d2150-f939-4f85-9882-09e922992762'	System	20 Aug 2020 16:02:40
User entered 'No (N)'	System	20 Aug 2020 16:02:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:33', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '554d2150-f939-4f85-9882-09e922992762'	System	20 Aug 2020 16:02:40
User entered 'No (N)'	System	20 Aug 2020 16:02:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '554d2150-f939-4f85-9882-09e922992762'	System	20 Aug 2020 16:02:40
User entered 'None (1)'	System	20 Aug 2020 16:02:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:44', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '554d2150-f939-4f85-9882-09e922992762' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 16:02:40
	System	20 Aug 2020 16:02:40

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 7'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:04', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '8b103704-4cb1-40a8-8def-0c13cd5a6af5'	System	21 Aug 2020 16:04:50
User entered 'None (1)'	System	21 Aug 2020 16:04:50

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '8b103704-4cb1-40a8-8def-0c13cd5a6af5' User entered 'No (N)'	System	21 Aug 2020 16:04:50
	System	21 Aug 2020 16:04:50

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:13', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '8b103704-4cb1-40a8-8def-0c13cd5a6af5'	System	21 Aug 2020 16:04:50
User entered 'No (N)'	System	21 Aug 2020 16:04:50

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '8b103704-4cb1-40a8-8def-0c13cd5a6af5'	System	21 Aug 2020 16:04:50
User entered 'None (1)'	System	21 Aug 2020 16:04:50

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:47', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '8b103704-4cb1-40a8-8def-0c13cd5a6af5' User entered '21 Aug 2020 12:04'	System	21 Aug 2020 16:04:50
	System	21 Aug 2020 16:04:50

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:12:58', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:13:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:13:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:13:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered 'None (0)'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:13:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb'	System	15 Aug 2020 14:13:27
User entered 'No (N)'	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-15T10:13:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6b4effce-67b5-41e4-95ca-57bb608c72bb' User entered '15 Aug 2020 10:13'	System	15 Aug 2020 14:13:27
	System	15 Aug 2020 14:13:27

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 09:51'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 12:21'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 1, after vaccination (at home)'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Aug 2020 13:16'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 2'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:42:47', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'None (0)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccae09ef6'	System	17 Aug 2020 00:43:45
User entered 'No interference with activity (1)'	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:21', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'None (0)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'None (0)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'None (0)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'None (0)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccaee09ef6' User entered 'No (N)'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-16T20:43:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '39e6cb9f-3f29-467b-90ab-04ccae09ef6' User entered '16 Aug 2020 20:43'	System	17 Aug 2020 00:43:45
	System	17 Aug 2020 00:43:45

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 3'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:41', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:46', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:49', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:53', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:24:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered 'None (0)'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:25:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3'	System	17 Aug 2020 16:25:22
User entered 'No (N)'	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-17T12:25:15', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce029a1-7381-4073-9fc7-31c81f39eac3' User entered '17 Aug 2020 12:25'	System	17 Aug 2020 16:25:22
	System	17 Aug 2020 16:25:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 4'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:05', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:13', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:21', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered 'None (0)'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:45:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da'	System	18 Aug 2020 18:46:05
User entered 'No (N)'	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-18T14:46:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '87fd4525-0965-438c-8cf4-7cac6e6274da' User entered '18 Aug 2020 14:46'	System	18 Aug 2020 18:46:05
	System	18 Aug 2020 18:46:05

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 5'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:53', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:10:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:04', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'None (0)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:23', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered 'No (N)'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-19T12:11:30', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '300676d9-70ca-4a4f-bc11-933f1b9b2f71' User entered '19 Aug 2020 12:11'	System	19 Aug 2020 16:11:33
	System	19 Aug 2020 16:11:33

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 6'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:01:52', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:04', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:07', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered 'None (0)'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188'	System	20 Aug 2020 16:03:19
User entered 'No (N)'	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-20T12:02:26', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '08fae117-8a66-4754-859a-acea0dea2188' User entered '20 Aug 2020 12:02'	System	20 Aug 2020 16:03:19
	System	20 Aug 2020 16:03:19

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 7'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:04:58', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:02', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:20', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'None (0)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered 'No (N)'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-08-21T12:05:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48a382b0-4e6b-416c-9bbe-8bd31afa595e' User entered '21 Aug 2020 12:05'	System	21 Aug 2020 16:05:43
	System	21 Aug 2020 16:05:43

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Aug 2020 12:00'	System	15 Aug 2020 13:55:22

US3202197

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '22 Aug 2020 11:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:10:13

US3202197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 11:44:24
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'yes due to business hours difference' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	21 Aug 2020 21:10:45
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Aug 2020 21:10:13
User entered '21 Aug 2020'	Lilian Nukuna (b) (4) (b) (4)	21 Aug 2020 21:10:13

US3202197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:10:13

US3202197

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Lilian Nukuna (b) (4)	21 Aug 2020 21:10:13

US3202197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Aug 2020 21:10:59

US3202197

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	21 Aug 2020 21:10:59

US3202197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:50:52

US3202197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:13:57
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CORRECT AS ENTERED' (Site from System).	Erica Osmundsen (b) (4)	14 Sep 2020 21:52:14
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 21:50:52
User entered '28 Aug 2020'	Erica Osmundsen (b) (4)	14 Sep 2020 21:50:52

US3202197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:50:52

US3202197

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'NO ANSWER'	Erica Osmundsen (b) (4)	14 Sep 2020 21:50:52

US3202197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:11:59

US3202197

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	14 Sep 2020 20:11:59

US3202197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:51:14

US3202197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:50:42
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CORRECT AS ENTERD' (Site from System).	Erica Osmundsen (b) (4)	14 Sep 2020 21:51:57
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 21:51:14
User entered '4 Sep 2020'	Erica Osmundsen (b) (4)	14 Sep 2020 21:51:14

US3202197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:51:26
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	14 Sep 2020 21:51:14

US3202197

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'NO ANSWER' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	14 Sep 2020 21:51:26
User entered empty.	Erica Osmundsen (b) (4)	14 Sep 2020 21:51:14

US3202197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:06

US3202197

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	14 Sep 2020 20:12:06

US3202197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:14

US3202197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:14

US3202197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:14

US3202197

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'VISIT2'	System	14 Sep 2020 20:12:14

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14:12'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '14 Sep 2020 14:12'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '36.9' C	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '76'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'bpm'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '20'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'breaths/min'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '116'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '69'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15:46'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '14 Sep 2020 15:46'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '36.6' C	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '66'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'bpm'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'breaths/min'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '124'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '68'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	14 Sep 2020 20:51:42

US3202197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:22

US3202197

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:22

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '15:06'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '14 Sep 2020 15:06'	System	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'ONCE'	System	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:42:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 20:12:46

US3202197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:03

US3202197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:03

US3202197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14:30'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:03

US3202197

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '14 Sep 2020 14:30'	System	14 Sep 2020 20:13:03

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '14:28'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '14 Sep 2020 14:28'	System	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered empty.	System	14 Sep 2020 20:13:28

US3202197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Sep 2020 20:13:34

US3202197

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	14 Sep 2020 20:13:34

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:24:30', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0d0f290b-079f-44c8-9366-ad46fdf9b9a0' User entered 'Yes (Y)'	System	14 Sep 2020 20:24:58
	System	14 Sep 2020 20:24:58

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:24:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0d0f290b-079f-44c8-9366-ad46fdf9b9a0' User entered '97.6'	System	14 Sep 2020 20:24:58
	System	14 Sep 2020 20:24:58

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:24:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0d0f290b-079f-44c8-9366-ad46fdf9b9a0'	System	14 Sep 2020 20:24:58
User entered 'No (N)'	System	14 Sep 2020 20:24:58

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:24:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0d0f290b-079f-44c8-9366-ad46fdf9b9a0'	System	14 Sep 2020 20:24:58
User entered '14 Sep 2020 16:24'	System	14 Sep 2020 20:24:58

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 15:26'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 17:56'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:28:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8b91f2b-08e9-43a6-b577-9d7388f5c93c' User entered 'Yes (Y)'	System	14 Sep 2020 23:29:49
	System	14 Sep 2020 23:29:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:29:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8b91f2b-08e9-43a6-b577-9d7388f5c93c' User entered '98.3'	System	14 Sep 2020 23:29:49
	System	14 Sep 2020 23:29:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:29:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8b91f2b-08e9-43a6-b577-9d7388f5c93c'	System	14 Sep 2020 23:29:49
User entered 'No (N)'	System	14 Sep 2020 23:29:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:29:44', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8b91f2b-08e9-43a6-b577-9d7388f5c93c' User entered '14 Sep 2020 19:29'	System	14 Sep 2020 23:29:49
	System	14 Sep 2020 23:29:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 18:51'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 2'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:02:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f5f50619-59df-4101-a040-727e1ff4970a' User entered 'Yes (Y)'	System	15 Sep 2020 16:04:46
	System	15 Sep 2020 16:04:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f5f50619-59df-4101-a040-727e1ff4970a' User entered '98.2'	System	15 Sep 2020 16:04:46
	System	15 Sep 2020 16:04:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:13', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f5f50619-59df-4101-a040-727e1ff4970a'	System	15 Sep 2020 16:04:46
User entered 'No (N)'	System	15 Sep 2020 16:04:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:23', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f5f50619-59df-4101-a040-727e1ff4970a' User entered '15 Sep 2020 12:03'	System	15 Sep 2020 16:04:46
	System	15 Sep 2020 16:04:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 3'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'fba920cb-d909-4f80-8f15-3b09b72c1139' User entered 'Yes (Y)'	System	17 Sep 2020 01:39:43
	System	17 Sep 2020 01:39:43

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:29', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'fba920cb-d909-4f80-8f15-3b09b72c1139' User entered '97.8'	System	17 Sep 2020 01:39:43
	System	17 Sep 2020 01:39:43

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:34', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'fba920cb-d909-4f80-8f15-3b09b72c1139'	System	17 Sep 2020 01:39:43
User entered 'No (N)'	System	17 Sep 2020 01:39:43

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'fba920cb-d909-4f80-8f15-3b09b72c1139' User entered '16 Sep 2020 21:39'	System	17 Sep 2020 01:39:43
	System	17 Sep 2020 01:39:43

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 4'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:03:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '9778887a-1321-4e33-816d-3e40c8d3a9f6' User entered 'Yes (Y)'	System	17 Sep 2020 16:04:59
	System	17 Sep 2020 16:04:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:03:09', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '9778887a-1321-4e33-816d-3e40c8d3a9f6' User entered '96.3'	System	17 Sep 2020 16:04:59
	System	17 Sep 2020 16:04:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:03:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '9778887a-1321-4e33-816d-3e40c8d3a9f6'	System	17 Sep 2020 16:04:59
User entered 'No (N)'	System	17 Sep 2020 16:04:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:03:45', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '9778887a-1321-4e33-816d-3e40c8d3a9f6' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:59
	System	17 Sep 2020 16:04:59

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 5'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:23', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '84005d42-3e83-410a-bec7-8eab67356fbf' User entered 'Yes (Y)'	System	18 Sep 2020 16:07:49
	System	18 Sep 2020 16:07:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '84005d42-3e83-410a-bec7-8eab67356fbf' User entered '98.5'	System	18 Sep 2020 16:07:49
	System	18 Sep 2020 16:07:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:36', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '84005d42-3e83-410a-bec7-8eab67356fbf' User entered 'No (N)'	System	18 Sep 2020 16:07:49
	System	18 Sep 2020 16:07:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '84005d42-3e83-410a-bec7-8eab67356fbf' User entered '18 Sep 2020 12:07'	System	18 Sep 2020 16:07:49
	System	18 Sep 2020 16:07:49

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 6'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4f19a448-ceb6-47dc-9cf1-b8530052404c' User entered 'Yes (Y)'	System	19 Sep 2020 16:10:39
	System	19 Sep 2020 16:10:39

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4f19a448-ceb6-47dc-9cf1-b8530052404c' User entered '98.5'	System	19 Sep 2020 16:10:39
	System	19 Sep 2020 16:10:39

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:23', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4f19a448-ceb6-47dc-9cf1-b8530052404c' User entered 'No (N)'	System	19 Sep 2020 16:10:39
	System	19 Sep 2020 16:10:39

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4f19a448-ceb6-47dc-9cf1-b8530052404c'	System	19 Sep 2020 16:10:39
User entered '19 Sep 2020 12:10'	System	19 Sep 2020 16:10:39

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 7'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:40:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '085db38c-1d1d-44e4-ac9d-1159337a4784' User entered 'Yes (Y)'	System	21 Sep 2020 02:41:19
	System	21 Sep 2020 02:41:19

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:05', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '085db38c-1d1d-44e4-ac9d-1159337a4784' User entered '98.0'	System	21 Sep 2020 02:41:19
	System	21 Sep 2020 02:41:19

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '085db38c-1d1d-44e4-ac9d-1159337a4784'	System	21 Sep 2020 02:41:19
User entered 'No (N)'	System	21 Sep 2020 02:41:19

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '085db38c-1d1d-44e4-ac9d-1159337a4784'	System	21 Sep 2020 02:41:19
User entered '20 Sep 2020 22:41'	System	21 Sep 2020 02:41:19

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f363bd6c-bda3-45b6-a760-50a62cc42817' User entered 'None (1)'	System	14 Sep 2020 20:25:45
	System	14 Sep 2020 20:25:45

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:16', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f363bd6c-bda3-45b6-a760-50a62cc42817' User entered 'No (N)'	System	14 Sep 2020 20:25:45
	System	14 Sep 2020 20:25:45

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f363bd6c-bda3-45b6-a760-50a62cc42817' User entered 'No (N)'	System	14 Sep 2020 20:25:45
	System	14 Sep 2020 20:25:45

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f363bd6c-bda3-45b6-a760-50a62cc42817'	System	14 Sep 2020 20:25:45
User entered 'None (1)'	System	14 Sep 2020 20:25:45

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:42', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f363bd6c-bda3-45b6-a760-50a62cc42817' User entered '14 Sep 2020 16:25'	System	14 Sep 2020 20:25:45
	System	14 Sep 2020 20:25:45

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 15:26'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 17:56'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:29:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b2dbc0d8-be62-4d18-b0db-2465102669f4'	System	14 Sep 2020 23:30:18
User entered 'None (1)'	System	14 Sep 2020 23:30:18

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b2dbc0d8-be62-4d18-b0db-2465102669f4'	System	14 Sep 2020 23:30:18
User entered 'No (N)'	System	14 Sep 2020 23:30:18

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:04', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b2dbc0d8-be62-4d18-b0db-2465102669f4' User entered 'No (N)'	System	14 Sep 2020 23:30:18
	System	14 Sep 2020 23:30:18

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:07', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b2dbc0d8-be62-4d18-b0db-2465102669f4'	System	14 Sep 2020 23:30:18
User entered 'None (1)'	System	14 Sep 2020 23:30:18

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b2dbc0d8-be62-4d18-b0db-2465102669f4'	System	14 Sep 2020 23:30:18
User entered '14 Sep 2020 19:30'	System	14 Sep 2020 23:30:18

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 18:51'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 2'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '684e719b-490b-474c-a2c5-48b0b2260192'	System	15 Sep 2020 16:05:09
User entered 'None (1)'	System	15 Sep 2020 16:05:09

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:35', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '684e719b-490b-474c-a2c5-48b0b2260192'	System	15 Sep 2020 16:05:09
User entered 'No (N)'	System	15 Sep 2020 16:05:09

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '684e719b-490b-474c-a2c5-48b0b2260192'	System	15 Sep 2020 16:05:09
User entered 'No (N)'	System	15 Sep 2020 16:05:09

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:45', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '684e719b-490b-474c-a2c5-48b0b2260192'	System	15 Sep 2020 16:05:09
User entered 'None (1)'	System	15 Sep 2020 16:05:09

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:03:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '684e719b-490b-474c-a2c5-48b0b2260192' User entered '15 Sep 2020 12:03'	System	15 Sep 2020 16:05:09
	System	15 Sep 2020 16:05:09

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 3'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:50', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6fcda203-359c-4612-a9ab-f019d1f7c8cd'	System	17 Sep 2020 01:40:12
User entered 'None (1)'	System	17 Sep 2020 01:40:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:54', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6fcda203-359c-4612-a9ab-f019d1f7c8cd'	System	17 Sep 2020 01:40:12
User entered 'No (N)'	System	17 Sep 2020 01:40:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:39:58', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6fcda203-359c-4612-a9ab-f019d1f7c8cd'	System	17 Sep 2020 01:40:12
User entered 'No (N)'	System	17 Sep 2020 01:40:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6fcda203-359c-4612-a9ab-f019d1f7c8cd'	System	17 Sep 2020 01:40:12
User entered 'None (1)'	System	17 Sep 2020 01:40:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:09', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6fcda203-359c-4612-a9ab-f019d1f7c8cd'	System	17 Sep 2020 01:40:12
User entered '16 Sep 2020 21:40'	System	17 Sep 2020 01:40:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 4'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:05:26', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0021c6ed-5c79-4134-9a19-d0df4e01b7ba'	System	17 Sep 2020 16:06:16
User entered 'None (1)'	System	17 Sep 2020 16:06:16

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:05:30', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0021c6ed-5c79-4134-9a19-d0df4e01b7ba' User entered 'No (N)'	System	17 Sep 2020 16:06:16
	System	17 Sep 2020 16:06:16

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:05:34', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0021c6ed-5c79-4134-9a19-d0df4e01b7ba' User entered 'No (N)'	System	17 Sep 2020 16:06:16
	System	17 Sep 2020 16:06:16

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:05:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0021c6ed-5c79-4134-9a19-d0df4e01b7ba' User entered 'None (1)'	System	17 Sep 2020 16:06:16
	System	17 Sep 2020 16:06:16

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:05:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0021c6ed-5c79-4134-9a19-d0df4e01b7ba' User entered '17 Sep 2020 12:05'	System	17 Sep 2020 16:06:16
	System	17 Sep 2020 16:06:16

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 5'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:50', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b56978a8-e62e-4c0b-a41f-74ff0e7f7deb'	System	18 Sep 2020 16:08:12
User entered 'None (1)'	System	18 Sep 2020 16:08:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:07:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b56978a8-e62e-4c0b-a41f-74ff0e7f7deb' User entered 'No (N)'	System	18 Sep 2020 16:08:12
	System	18 Sep 2020 16:08:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b56978a8-e62e-4c0b-a41f-74ff0e7f7deb' User entered 'No (N)'	System	18 Sep 2020 16:08:12
	System	18 Sep 2020 16:08:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:04', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b56978a8-e62e-4c0b-a41f-74ff0e7f7deb'	System	18 Sep 2020 16:08:12
User entered 'None (1)'	System	18 Sep 2020 16:08:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b56978a8-e62e-4c0b-a41f-74ff0e7f7deb' User entered '18 Sep 2020 12:08'	System	18 Sep 2020 16:08:12
	System	18 Sep 2020 16:08:12

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 6'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:09:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6263d5ff-db26-4651-b93d-94cc8a1cb37b'	System	19 Sep 2020 16:10:05
User entered 'None (1)'	System	19 Sep 2020 16:10:05

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:09:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6263d5ff-db26-4651-b93d-94cc8a1cb37b' User entered 'No (N)'	System	19 Sep 2020 16:10:05
	System	19 Sep 2020 16:10:05

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:09:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6263d5ff-db26-4651-b93d-94cc8a1cb37b' User entered 'No (N)'	System	19 Sep 2020 16:10:05
	System	19 Sep 2020 16:10:05

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:09:53', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6263d5ff-db26-4651-b93d-94cc8a1cb37b' User entered 'None (1)'	System	19 Sep 2020 16:10:05
	System	19 Sep 2020 16:10:05

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '6263d5ff-db26-4651-b93d-94cc8a1cb37b' User entered '19 Sep 2020 12:10'	System	19 Sep 2020 16:10:05
	System	19 Sep 2020 16:10:05

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 7'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cb11877f-14ee-409b-a88f-18dc1b554ce8'	System	21 Sep 2020 02:42:07
User entered 'None (1)'	System	21 Sep 2020 02:42:07

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cb11877f-14ee-409b-a88f-18dc1b554ce8'	System	21 Sep 2020 02:42:07
User entered 'No (N)'	System	21 Sep 2020 02:42:07

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cb11877f-14ee-409b-a88f-18dc1b554ce8'	System	21 Sep 2020 02:42:07
User entered 'No (N)'	System	21 Sep 2020 02:42:07

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:41:36', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cb11877f-14ee-409b-a88f-18dc1b554ce8'	System	21 Sep 2020 02:42:07
User entered 'None (1)'	System	21 Sep 2020 02:42:07

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cb11877f-14ee-409b-a88f-18dc1b554ce8' User entered '20 Sep 2020 22:42'	System	21 Sep 2020 02:42:07
	System	21 Sep 2020 02:42:07

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:25:58', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:02', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:12', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:15', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:20', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc' User entered 'None (0)'	System	14 Sep 2020 20:26:34
	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:25', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc'	System	14 Sep 2020 20:26:34
User entered 'No (N)'	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T16:26:29', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aa392cf8-62ef-4fdd-9329-a08044ee93bc'	System	14 Sep 2020 20:26:34
User entered '14 Sep 2020 16:26'	System	14 Sep 2020 20:26:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 15:26'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 17:56'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:20', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:34', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'None (0)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:42', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered 'No (N)'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-14T19:30:50', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'd11dcb4f-658c-4dee-9664-5dd66029284d' User entered '14 Sep 2020 19:30'	System	14 Sep 2020 23:31:25
	System	14 Sep 2020 23:31:25

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '14 Sep 2020 18:51'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 2'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:17', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered 'None (0)'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec'	System	15 Sep 2020 16:05:34
User entered 'No (N)'	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-15T12:04:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e3cce2ae-5696-4841-b86f-31ed4c69b9ec' User entered '15 Sep 2020 12:04'	System	15 Sep 2020 16:05:34
	System	15 Sep 2020 16:05:34

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 3'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:16', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'None (0)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:25', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35' User entered 'None (0)'	System	17 Sep 2020 01:41:10
	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'None (0)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'None (0)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:34', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'None (0)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'None (0)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:40:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered 'No (N)'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-16T21:41:07', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '62b74f4f-e25a-4d64-a79a-d180d4defc35'	System	17 Sep 2020 01:41:10
User entered '16 Sep 2020 21:41'	System	17 Sep 2020 01:41:10

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 4'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:06:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:06:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:06:59', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:07:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:07:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:07:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'None (0)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:07:30', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered 'No (N)'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-17T12:08:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7ce7517f-138b-4274-8312-2d1a363be324' User entered '17 Sep 2020 12:08'	System	17 Sep 2020 16:08:04
	System	17 Sep 2020 16:08:04

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 5'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:16', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'None (0)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'None (0)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'None (0)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:24', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82' User entered 'None (0)'	System	18 Sep 2020 16:08:51
	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'None (0)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'None (0)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:38', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered 'No (N)'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-18T12:08:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3704ed9c-eb0d-4ef8-920b-35ef2e5e7a82'	System	18 Sep 2020 16:08:51
User entered '18 Sep 2020 12:08'	System	18 Sep 2020 16:08:51

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 6'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:43', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:45', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:49', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'None (0)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:10:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered 'No (N)'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-19T12:11:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'bd5942ed-0fce-4f8f-a3ad-c6320ba5eec3' User entered '19 Sep 2020 12:11'	System	19 Sep 2020 16:11:11
	System	19 Sep 2020 16:11:11

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	14 Sep 2020 20:12:46
User entered 'Day 7'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:08', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:22', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:25', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered 'None (0)'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:31', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88'	System	21 Sep 2020 02:42:44
User entered 'No (N)'	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-09-20T22:42:42', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4b3c079c-1e69-4970-a8ac-84a683220c88' User entered '20 Sep 2020 22:42'	System	21 Sep 2020 02:42:44
	System	21 Sep 2020 02:42:44

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 20:12:46

US3202197

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:42:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 20:12:46

US3202197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 19:47:56

US3202197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '21 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 19:47:56

US3202197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 19:47:56

US3202197

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	Lilian Nukuna (b) (4)	21 Sep 2020 19:47:56

US3202197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	21 Sep 2020 19:48:02

US3202197

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	21 Sep 2020 19:48:02

US3202197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:33:43

US3202197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '28 Sep 2020'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:33:43

US3202197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:33:43

US3202197

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:33:43

US3202197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	28 Sep 2020 20:33:49

US3202197

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	28 Sep 2020 20:33:49

US3202197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:27

US3202197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:27

US3202197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:27

US3202197

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:27

US3202197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:31

US3202197

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	13 Oct 2020 18:46:31

US3202197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:49

US3202197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:49

US3202197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:46:49

US3202197

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'VISIT3'	System	13 Oct 2020 18:46:49

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '13:14'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '12 Oct 2020 13:14'	System	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '36.8' C	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '68'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'bpm'	System	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'breaths/min'	System	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '110'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '64'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'mmHg'	System	13 Oct 2020 18:47:56

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33

US3202197

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33

US3202197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:01

US3202197

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:01

US3202197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:13

US3202197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '12 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:13

US3202197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered '13:22'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:13

US3202197

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '12 Oct 2020 13:22'	System	13 Oct 2020 18:48:13

US3202197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:36
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	13 Oct 2020 18:48:18

US3202197

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered '1'	System	13 Oct 2020 18:48:18

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 64'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-17T21:26:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7169f9ff-e2aa-42b7-ab04-36fbfd925074'	System	18 Oct 2020 01:27:41
User entered 'No (N)'	System	18 Oct 2020 01:27:41

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-17T21:27:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7169f9ff-e2aa-42b7-ab04-36fbfd925074'	System	18 Oct 2020 01:27:41
User entered 'No (N)'	System	18 Oct 2020 01:27:41

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-17T21:27:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '7169f9ff-e2aa-42b7-ab04-36fbfd925074' User entered '17 Oct 2020 21:27:18'	System	18 Oct 2020 01:27:41
	System	18 Oct 2020 01:27:41

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '15 Oct 2020 00:01'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '19 Oct 2020 23:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 71'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-23T09:15:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e0783025-c848-44ad-8c0f-8f2ef54b7955'	System	23 Oct 2020 13:15:50
User entered 'No (N)'	System	23 Oct 2020 13:15:50

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-23T09:15:37', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e0783025-c848-44ad-8c0f-8f2ef54b7955'	System	23 Oct 2020 13:15:50
User entered 'No (N)'	System	23 Oct 2020 13:15:50

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-23T09:15:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e0783025-c848-44ad-8c0f-8f2ef54b7955' User entered '23 Oct 2020 09:15:48'	System	23 Oct 2020 13:15:50
	System	23 Oct 2020 13:15:50

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '22 Oct 2020 00:01'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '26 Oct 2020 23:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 78'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-30T11:54:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f7d275c6-938f-4526-87e9-c4b161ea39a9'	System	30 Oct 2020 15:55:02
User entered 'No (N)'	System	30 Oct 2020 15:55:02

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-30T11:54:53', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f7d275c6-938f-4526-87e9-c4b161ea39a9'	System	30 Oct 2020 15:55:02
User entered 'No (N)'	System	30 Oct 2020 15:55:02

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-10-30T11:54:57', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f7d275c6-938f-4526-87e9-c4b161ea39a9' User entered '30 Oct 2020 11:54:57'	System	30 Oct 2020 15:55:02
	System	30 Oct 2020 15:55:02

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '29 Oct 2020 00:01'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '02 Nov 2020 23:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 92'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-12T20:56:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f4fe43d7-e4d3-4129-90b2-925ed511a48e'	System	13 Nov 2020 01:57:38
User entered 'No (N)'	System	13 Nov 2020 01:57:38

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-12T20:57:19', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f4fe43d7-e4d3-4129-90b2-925ed511a48e'	System	13 Nov 2020 01:57:38
User entered 'No (N)'	System	13 Nov 2020 01:57:38

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-12T20:57:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f4fe43d7-e4d3-4129-90b2-925ed511a48e' User entered '12 Nov 2020 20:57:32'	System	13 Nov 2020 01:57:38
	System	13 Nov 2020 01:57:38

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '12 Nov 2020 00:01'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:37:01
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '16 Nov 2020 23:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36
Data entry locked.	System	15 Aug 2020 13:55:22
User entered 'Day 99'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '19 Nov 2020 00:01'	System	15 Aug 2020 13:55:22

US3202197

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:14:36
Data entry locked.	System	15 Aug 2020 13:55:22
User entered '23 Nov 2020 23:59'	System	15 Aug 2020 13:55:22

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-20T19:57:47', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48e355ef-54b3-41c6-97c6-a3eb923ba990' User entered 'No (N)'	System	21 Nov 2020 00:58:20
	System	21 Nov 2020 00:58:20

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-20T19:58:02', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48e355ef-54b3-41c6-97c6-a3eb923ba990'	System	21 Nov 2020 00:58:20
User entered 'No (N)'	System	21 Nov 2020 00:58:20

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-20T19:58:15', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '48e355ef-54b3-41c6-97c6-a3eb923ba990'	System	21 Nov 2020 00:58:20
User entered '20 Nov 2020 19:58:15'	System	21 Nov 2020 00:58:20

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-24T22:28:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2871aee0-6f9f-460d-8cec-3282151e3ac3'	System	25 Nov 2020 03:30:18
User entered 'No (N)'	System	25 Nov 2020 03:30:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-24T22:30:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2871aee0-6f9f-460d-8cec-3282151e3ac3'	System	25 Nov 2020 03:30:18
User entered 'No (N)'	System	25 Nov 2020 03:30:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-24T22:30:15', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2871aee0-6f9f-460d-8cec-3282151e3ac3' User entered '24 Nov 2020 22:30:15'	System	25 Nov 2020 03:30:18
	System	25 Nov 2020 03:30:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-30T18:19:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cc2253d9-21a3-4ded-a89c-826c247d52a0' User entered 'No (N)'	System	30 Nov 2020 23:20:05
	System	30 Nov 2020 23:20:05

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-30T18:19:55', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cc2253d9-21a3-4ded-a89c-826c247d52a0' User entered 'No (N)'	System	30 Nov 2020 23:20:05

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-11-30T18:19:59', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'cc2253d9-21a3-4ded-a89c-826c247d52a0' User entered '30 Nov 2020 18:19:59'	System	30 Nov 2020 23:20:05
	System	30 Nov 2020 23:20:05

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-07T16:49:41', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aff77aca-4806-472a-acf9-d3fa6b5f81e5'	System	07 Dec 2020 21:49:56
User entered 'No (N)'	System	07 Dec 2020 21:49:56

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-07T16:49:48', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aff77aca-4806-472a-acf9-d3fa6b5f81e5'	System	07 Dec 2020 21:49:56
User entered 'No (N)'	System	07 Dec 2020 21:49:56

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-07T16:49:52', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'aff77aca-4806-472a-acf9-d3fa6b5f81e5' User entered '07 Dec 2020 16:49:52'	System	07 Dec 2020 21:49:56
	System	07 Dec 2020 21:49:56

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-16T17:04:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2e56cfff-a484-440d-90c4-c37b43e62fc6'	System	16 Dec 2020 22:05:18
User entered 'No (N)'	System	16 Dec 2020 22:05:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-16T17:05:06', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2e56cfff-a484-440d-90c4-c37b43e62fc6'	System	16 Dec 2020 22:05:18
User entered 'No (N)'	System	16 Dec 2020 22:05:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-16T17:05:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '2e56cfff-a484-440d-90c4-c37b43e62fc6' User entered '16 Dec 2020 17:05:14'	System	16 Dec 2020 22:05:18
	System	16 Dec 2020 22:05:18

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-21T22:38:51', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '79c0ecfc-61ee-44ae-83bd-ce896c69f46f' User entered 'No (N)'	System	22 Dec 2020 03:39:07
	System	22 Dec 2020 03:39:07

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-21T22:38:56', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '79c0ecfc-61ee-44ae-83bd-ce896c69f46f' User entered 'No (N)'	System	22 Dec 2020 03:39:07

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-21T22:39:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '79c0ecfc-61ee-44ae-83bd-ce896c69f46f' User entered '21 Dec 2020 22:39:03'	System	22 Dec 2020 03:39:07

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-28T22:47:38', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b584db8c-9316-4162-bb8c-2177bb7afdf5'	System	29 Dec 2020 03:48:21
User entered 'No (N)'	System	29 Dec 2020 03:48:21

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-28T22:48:07', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b584db8c-9316-4162-bb8c-2177bb7afdf5'	System	29 Dec 2020 03:48:21
User entered 'No (N)'	System	29 Dec 2020 03:48:21

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2020-12-28T22:48:18', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b584db8c-9316-4162-bb8c-2177bb7afdf5' User entered '28 Dec 2020 22:48:18'	System	29 Dec 2020 03:48:21

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-04T17:42:59', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0edec803-12d0-4d3a-ba6b-c3a08c157811' User entered 'No (N)'	System	04 Jan 2021 22:43:16
	System	04 Jan 2021 22:43:16

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-04T17:43:10', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0edec803-12d0-4d3a-ba6b-c3a08c157811' User entered 'No (N)'	System	04 Jan 2021 22:43:16
	System	04 Jan 2021 22:43:16

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-04T17:43:14', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '0edec803-12d0-4d3a-ba6b-c3a08c157811' User entered '04 Jan 2021 17:43:14'	System	04 Jan 2021 22:43:16
	System	04 Jan 2021 22:43:16

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-11T09:59:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'ea142320-8a3b-44e9-8762-0cc685da2610'	System	11 Jan 2021 14:59:50
User entered 'No (N)'	System	11 Jan 2021 14:59:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-11T09:59:39', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'ea142320-8a3b-44e9-8762-0cc685da2610'	System	11 Jan 2021 14:59:50
User entered 'No (N)'	System	11 Jan 2021 14:59:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-11T09:59:45', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'ea142320-8a3b-44e9-8762-0cc685da2610' User entered '11 Jan 2021 09:59:45'	System	11 Jan 2021 14:59:50
	System	11 Jan 2021 14:59:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-21T23:31:35', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '35a621f8-3de5-422c-8812-52f2c526659a' User entered 'No (N)'	System	22 Jan 2021 04:31:50
	System	22 Jan 2021 04:31:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-21T23:31:40', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '35a621f8-3de5-422c-8812-52f2c526659a' User entered 'No (N)'	System	22 Jan 2021 04:31:50
	System	22 Jan 2021 04:31:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-01-21T23:31:45', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '35a621f8-3de5-422c-8812-52f2c526659a' User entered '21 Jan 2021 23:31:45'	System	22 Jan 2021 04:31:50
	System	22 Jan 2021 04:31:50

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-02T12:42:54', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '53799bf6-646e-45b5-a926-d47697d7de6c' User entered 'No (N)'	System	02 Feb 2021 17:43:13
	System	02 Feb 2021 17:43:13

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-02T12:43:03', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '53799bf6-646e-45b5-a926-d47697d7de6c' User entered 'No (N)'	System	02 Feb 2021 17:43:13

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-02T12:43:11', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '53799bf6-646e-45b5-a926-d47697d7de6c'	System	02 Feb 2021 17:43:13
User entered '02 Feb 2021 12:43:11'	System	02 Feb 2021 17:43:13

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-08T20:54:20', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '20cc6bfe-e2fb-434f-b928-9b8f732fd2a9' User entered 'No (N)'	System	09 Feb 2021 01:54:37
	System	09 Feb 2021 01:54:37

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-08T20:54:27', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '20cc6bfe-e2fb-434f-b928-9b8f732fd2a9' User entered 'No (N)'	System	09 Feb 2021 01:54:37

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-08T20:54:32', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '20cc6bfe-e2fb-434f-b928-9b8f732fd2a9' User entered '08 Feb 2021 20:54:32'	System	09 Feb 2021 01:54:37

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-15T20:03:01', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '5616c3b8-f325-4a9d-8b93-4100e2ae3156' User entered 'No (N)'	System	16 Feb 2021 01:04:32
	System	16 Feb 2021 01:04:32

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-15T20:03:28', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '5616c3b8-f325-4a9d-8b93-4100e2ae3156' User entered 'No (N)'	System	16 Feb 2021 01:04:32
	System	16 Feb 2021 01:04:32

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-02-15T20:03:36', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '5616c3b8-f325-4a9d-8b93-4100e2ae3156' User entered '15 Feb 2021 20:03:36'	System	16 Feb 2021 01:04:32
	System	16 Feb 2021 01:04:32

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-03T12:17:15-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4fbb18f8-8e48-4aac-b22d-f9e2f0698adb' User entered 'No (N)'	System	03 Mar 2021 17:28:00
	System	03 Mar 2021 17:28:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-03T12:17:22-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4fbb18f8-8e48-4aac-b22d-f9e2f0698adb' User entered 'No (N)'	System	03 Mar 2021 17:28:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-03T12:17:26-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '4fbb18f8-8e48-4aac-b22d-f9e2f0698adb' User entered '03 Mar 2021 12:17:26'	System	03 Mar 2021 17:28:00
	System	03 Mar 2021 17:28:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-08T19:20:52-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f15332ef-0d09-4c4e-a505-a14b205fbe98'	System	09 Mar 2021 00:21:11
User entered 'No (N)'	System	09 Mar 2021 00:21:11

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-08T19:20:59-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f15332ef-0d09-4c4e-a505-a14b205fbe98'	System	09 Mar 2021 00:21:11
User entered 'No (N)'	System	09 Mar 2021 00:21:11

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-08T19:21:04-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'f15332ef-0d09-4c4e-a505-a14b205fbe98'	System	09 Mar 2021 00:21:11
User entered '08 Mar 2021 19:21:04'	System	09 Mar 2021 00:21:11

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-15T12:14:25-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1262c4b7-9701-4652-9f1d-07cb09e422bf'	System	15 Mar 2021 16:20:03
User entered 'No (N)'	System	15 Mar 2021 16:20:03

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-15T12:14:34-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1262c4b7-9701-4652-9f1d-07cb09e422bf'	System	15 Mar 2021 16:20:03
User entered 'No (N)'	System	15 Mar 2021 16:20:03

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-15T12:14:42-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '1262c4b7-9701-4652-9f1d-07cb09e422bf' User entered '15 Mar 2021 12:14:42'	System	15 Mar 2021 16:20:03
	System	15 Mar 2021 16:20:03

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-24T19:30:40-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3fb74d7b-9d9d-4516-ba95-d089825175e8'	System	24 Mar 2021 23:31:00
User entered 'No (N)'	System	24 Mar 2021 23:31:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-24T19:30:44-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3fb74d7b-9d9d-4516-ba95-d089825175e8'	System	24 Mar 2021 23:31:00
User entered 'No (N)'	System	24 Mar 2021 23:31:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-24T19:30:55-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '3fb74d7b-9d9d-4516-ba95-d089825175e8'	System	24 Mar 2021 23:31:00
User entered '24 Mar 2021 19:30:55'	System	24 Mar 2021 23:31:00

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-30T19:43:33-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '36998b9f-fe9b-4a2e-a0b8-78a555aaf821'	System	30 Mar 2021 23:44:08
User entered 'No (N)'	System	30 Mar 2021 23:44:08

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-30T19:43:38-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '36998b9f-fe9b-4a2e-a0b8-78a555aaf821'	System	30 Mar 2021 23:44:08
User entered 'No (N)'	System	30 Mar 2021 23:44:08

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-30T19:44:01-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: '36998b9f-fe9b-4a2e-a0b8-78a555aaf821' User entered '30 Mar 2021 19:44:01'	System	30 Mar 2021 23:44:08
	System	30 Mar 2021 23:44:08

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-05T20:48:04-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8bff885-8c32-408b-8770-9d540198f9a9'	System	06 Apr 2021 00:48:38
User entered 'No (N)'	System	06 Apr 2021 00:48:38

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-05T20:48:12-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8bff885-8c32-408b-8770-9d540198f9a9'	System	06 Apr 2021 00:48:38
User entered 'No (N)'	System	06 Apr 2021 00:48:38

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-05T20:48:23-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'b8bff885-8c32-408b-8770-9d540198f9a9'	System	06 Apr 2021 00:48:38
User entered '05 Apr 2021 20:48:23'	System	06 Apr 2021 00:48:38

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-26T13:56:30-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e4d234d7-6342-4608-a453-cab7fdac3b8e' User entered 'No (N)'	System	26 Apr 2021 17:56:45
	System	26 Apr 2021 17:56:45

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

Have you been exposed to someone with 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 (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-26T13:56:36-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e4d234d7-6342-4608-a453-cab7fdac3b8e' User entered 'No (N)'	System	26 Apr 2021 17:56:45
	System	26 Apr 2021 17:56:45

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-04-26T13:56:41-04:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'e4d234d7-6342-4608-a453-cab7fdac3b8e' User entered '26 Apr 2021 13:56:41'	System	26 Apr 2021 17:56:45
	System	26 Apr 2021 17:56:45

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 08:14:36

US3202197

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:42:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:14:36
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 08:14:36

US3202197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:42:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-03T12:17:34-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'becc8895-ac4a-4e59-adb2-8fd37c01a393'	System	03 Mar 2021 17:28:06
User entered 'No (N)'	System	03 Mar 2021 17:28:06

US3202197

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:42:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FBE3D1FE-BFDF-4C86-8ED1-828C96B228D1)', Time: '2021-03-03T12:17:38-05:00', User OID: 'PatientReportedOutcome (US3202197)', ODM File OID: 'becc8895-ac4a-4e59-adb2-8fd37c01a393'	System	03 Mar 2021 17:28:06
User entered '03 Mar 2021 12:17:38'	System	03 Mar 2021 17:28:06

US3202197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Mar 2021 18:00:26

US3202197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered '09 Nov 2020'	(b) (4) zackery harmon (b) (4)	07 Mar 2021 18:00:26
	(b) (4)	

US3202197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4) (b) (4)	07 Mar 2021 18:00:26

US3202197

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Mar 2021 18:00:26
	(b) (4)	

US3202197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:45:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:19

US3202197

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:48:33
User entered 'I'	System	14 Dec 2020 14:51:19

US3202197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:30

US3202197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:30

US3202197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:30

US3202197

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:30

US3202197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:51:33

US3202197

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User entered 'I'	System	14 Dec 2020 14:51:33

US3202197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Feb 2021 22:49:55

US3202197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:12:58
User entered '11 Jan 2021' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	26 Feb 2021 22:50:35
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	26 Feb 2021 22:50:01
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	26 Feb 2021 22:49:55
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	26 Feb 2021 22:49:55

US3202197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	26 Feb 2021 22:49:55

US3202197

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Feb 2021 22:49:55
	(b) (4)	

US3202197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	26 Feb 2021 22:50:38

US3202197

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User entered 'I'	System	26 Feb 2021 22:50:38

US3202197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	26 Feb 2021 22:50:55
User entered 'Yes (Y)'	System	26 Feb 2021 22:50:47
	zackery harmon (b) (4)	26 Feb 2021 22:50:47
	(b) (4)	

US3202197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:18:01
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow ' (Site from System).	zackery harmon (b) (4) (b) (4)	26 Feb 2021 22:50:59
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Feb 2021 22:50:47
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	26 Feb 2021 22:50:47

US3202197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	zackery harmon (b) (4)	26 Feb 2021 22:50:55
User entered empty.	(b) (4)	
	zackery harmon (b) (4)	26 Feb 2021 22:50:47
	(b) (4)	

US3202197

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) zackery harmon (b) (4)	26 Feb 2021 22:50:47
	(b) (4)	

US3202197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Mar 2021 17:59:56

US3202197

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:46
User entered 'I'	System	07 Mar 2021 17:59:56

US3202197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:51:35

US3202197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:51:35

US3202197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[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 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:51:35

US3202197

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered 'VISIT4'	System	11 Mar 2021 21:51:35

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered empty.	System	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered empty.	System	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered empty.	System	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered empty.	System	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered empty.	System	31 Mar 2021 21:50:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57

US3202197

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:42:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57

US3202197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:51:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:42:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:51:43

US3202197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:52:54

US3202197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:52:54

US3202197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '12:58'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:52:54

US3202197

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered '11 Mar 2021 12:58'	System	11 Mar 2021 21:52:54

US3202197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	11 Mar 2021 21:55:14

US3202197

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:57
User entered 'I'	System	11 Mar 2021 21:55:14

US3202197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 17:14:58

US3202197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
	(b) (4)	
User entered '14 Apr 2021'	Lilian Nukuna (b) (4)	14 Apr 2021 17:14:58

US3202197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	14 Apr 2021 17:14:58

US3202197

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:42:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Apr 2021 17:14:58

US3202197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 17:15:04

US3202197

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:42:37

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 17:15:04

US3202197

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

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:31

US3202197

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

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:31

US3202197

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

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:31

US3202197

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

Form: Visit Date

Generated On: 09 Jun 2021 15:42:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 18:17:31

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:33
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 16:42:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:50:33

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 18:47:56
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:33
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 'done' (Site from DM).	Teresa Deese (b) (4)	22 Apr 2021 16:43:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 16:42:50
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 08:47:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:50:33

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:59:55
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

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

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:59:55
User entered 'mRNA-1273 (mRNA-1273)'	Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:17:53

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User entered empty.	System	14 Jan 2021 18:17:53

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:42:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User entered empty.	System	14 Jan 2021 18:17:53

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:34

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:34

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11:34'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:34

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:42:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User entered '11 Jan 2021 11:34'	System	14 Jan 2021 18:21:34

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:46

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11 Jan 2021'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:46

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User entered '11:29'	(b) (4) Teresa Deese (b) (4)	14 Jan 2021 18:21:46

US3202197

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:42:37

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:11
User entered '11 Jan 2021 11:29'	System	14 Jan 2021 18:21:46

US3202197

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:42:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:57:48
Signature has been broken.	Erica Osmundsen (b) (4)	05 Apr 2021 21:09:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:09:38
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:09:41
User closed query 'please confirm that surgery did not meet SAE reporting requirements. Were hospital/consult records requested?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:30:44
Query 'please confirm that surgery did not meet SAE reporting requirements. Were hospital/consult records requested?' answered with 'was not overnight stay' (Site from CRA).	Teresa Deese (b) (4)	02 Mar 2021 20:13:00
User opened query 'please confirm that surgery did not meet SAE reporting requirements. Were hospital/consult records requested?' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 21:03:48
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Feb 2021 16:34:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Feb 2021 16:34:31
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Feb 2021 16:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	14 Jan 2021 18:22:31
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:18:41

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:01:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:26
User entered	System	06 Apr 2021 18:10:23
'USA-US128-2021-mRNA-1273-P301000015'		
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 18:10:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 19:46:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 19:46:21
Data point term sent to Coder	System	12 Apr 2021 18:32:35
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Data point term sent to Coder	System	12 Apr 2021 18:06:47
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:48:51
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 10:09:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 10:09:52
Data point term sent to Coder	System	05 Apr 2021 21:13:06
User entered 'RIGHT CAROTID STENOSIS'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:49:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the onset date for the event. It is reported that right carotid stenosis was first diagnosed in Jun 2020, yet it is reported as start date of 21 Oct 2020. Please re eval adverse event and provide events leading up to the endarectomy.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:46:56
Query 'PV Query: Please provide the onset date for the event. It is reported that right carotid stenosis was first diagnosed in Jun 2020, yet it is reported as start date of 21 Oct 2020. Please re eval adverse event and provide events leading up to the endarectomy.'	Erica Osmundsen (b) (4)	15 Apr 2021 16:19:13
answered with 'PER GUIDANCE FORM CRA, ANY CONDITION THAT IS ACTUALLY A NON-WORSENING MEDICAL HISTORY CONDITION THAT IS REQUIRED TO BE REPORTED AS AN SAE BECAUSE OF THE HOSPITALIZATION REQUIRED FOR SURGICAL INTERVENTION OR TREATMENT SHOULD LIST START DATE AS THE DATE OF THE ADMISSION TO HOSPITAL FOR THE SURGERY. THE SUBJECT DISCLOSED CONDITION AT START OF STUDY AND IT HAD NOT WORSENERED AT TIME OF SURGERIES. HE WAS TOLD THAT HE'D NEED SURGERY AT TIME OF DIAGNOSIS BUT PANDEMIC DELAYED SURGICAL TREATMENT.' (Site from Safety).		
User opened query 'PV Query: Please provide the onset date for the event. It is reported that right carotid stenosis was first diagnosed in Jun 2020, yet it is reported as start date of 21 Oct 2020. Please re eval adverse event and provide events leading up to the endarectomy.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:08:51
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
Query 'source = 15Jun20, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 13:49:08
User opened query 'source = 15Jun20, please verify' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 13:48:22
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		05 Apr 2021 21:20:20
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	05 Apr 2021 21:20:20
User entered '21 Oct 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:20:20
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	05 Apr 2021 21:12:23
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		05 Apr 2021 21:12:23
User entered '15 Jun 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User entered empty.	System	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:06:05
User entered empty.	System	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '22 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:08:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:47:03
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. [Only if the symptoms are reported as such]' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:47:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'ADDED THE LIMITED INFORMATION AVAILABLE IN RECORDS' (Site from Safety).	Erica Osmundsen (b) (4)	15 Apr 2021 21:37:19
DataPoint Un-verified.	Erica Osmundsen (b) (4)	15 Apr 2021 21:36:48
Signature has been broken.	Erica Osmundsen (b) (4)	15 Apr 2021 21:36:48

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD ENDARTERECTOMY DUE TO MEDICAL HISTORY--CONDITION NOT WORSENING SO UNCLEAR HOW TO REPORT AS AN AE, BUT PROCEDURE TO TREAT CONDITION REQUIRED OVERNIGHT HOSPITALIZATION (<24 HOURS) THUS REPORTED AS SAE PER PROTOCOL GUIDELINES FOR HOSPITALIZATIONS. NO LABS INCLUDED IN RECORDS OTHER THAN PATHOLOGY ON THE PLAQUE REMOVED AND NO MALIGNANCY NOTED. NO COVID-19 TESTS NOTED, DIAGNOSTIC SUMMARY IN OPERATIVE REPORT MENTIONS THAT RIGHT CAROTID WAS WORSE (PATIENT REPORTED 100% OCCLUDED) PER ECHO AND CAROTID ULTRASOUND DONE IN JUNE 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 21:36:48
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. [Only if the symptoms are reported as such]' answered with 'SUBJECT WAS NOT TESTED FOR COVID-19 PER RECORDS RECEIVED AND NO SYMPTOMS WERE PRESENT.' (Site from Safety).	Erica Osmundsen (b) (4)	15 Apr 2021 16:21:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:07:02
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results. [Only if the symptoms are reported as such]' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:06:17
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 18:31:43

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'SUBJECT HAD ENDARTERECTOMY DUE TO MEDICAL HISTORY--CONDITION NOT WORSENING SO UNCLEAR HOW TO REPORT AS AN AE, BUT PROCEDURE TO TREAT CONDITION REQUIRED OVERNIGHT HOSPITALIZATION (<24 HOURS) THUS REPORTED AS SAE PER PROTOCOL GUIDELINES FOR HOSPITALIZATIONS.'	Erica Osmundsen (b) (4)	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:06:05
User entered '1'	System	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:06:05
User entered '1'	System	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:42:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:31:43
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:06:05
User entered '0'	System	05 Apr 2021 21:12:23

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:01:38
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:31:17
User entered	System	06 Apr 2021 19:30:22
'USA-US128-2021-mRNA-1273-P301000017'		
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 19:30:22

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 19:46:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 19:46:21
Data point term sent to Coder	System	12 Apr 2021 18:32:31
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Data point term sent to Coder	System	12 Apr 2021 18:06:47
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery stenosis, LLT: Carotid artery stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 21:33:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 21:33:11
Data point term sent to Coder	System	05 Apr 2021 21:20:23
User entered 'LEFT CAROTID STENOSIS'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:51:26
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	05 Apr 2021 21:20:49
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	05 Apr 2021 21:20:49
User entered '19 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:20:49
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	05 Apr 2021 21:19:33
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	05 Apr 2021 21:19:33
User entered '15 Jun 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:32:02
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4) [REDACTED]	12 Apr 2021 18:05:51
User entered empty.	System	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User entered empty.	System	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
User closed query 'PV Query: If this condition is not new or worsening, please confirm if this is a valid reportable SAE. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:15:53
Query 'PV Query: If this condition is not new or worsening, please confirm if this is a valid reportable SAE. ' answered with 'this is SAE' (Site from Safety).	Teresa Deese (b) (4)	12 Apr 2021 18:32:19
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User opened query 'PV Query: If this condition is not new or worsening, please confirm if this is a valid reportable SAE. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 11:24:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '20 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'I'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:30:55
DataPoint activated with code reason code Data required.	(b) (4) Teresa Deese (b) (4)	12 Apr 2021 18:32:02
Signature has been broken.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:51:26
User entered 'SUBJECT HAD ENDARTERECTOMY DUE TO MEDICAL HISTORY--CONDITION NOT WORSENING SO UNCLEAR HOW TO REPORT AS AN AE, BUT PROCEDURE TO TREAT CONDITION REQUIRED OVERNIGHT HOSPITALIZATION (<24 HOURS) THUS REPORTED AS SAE PER PROTOCOL GUIDELINES FOR HOSPITALIZATIONS.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:20:49
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User entered '1'	System	05 Apr 2021 21:19:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User entered '1'	System	05 Apr 2021 21:19:33

US3202197

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:42:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Teresa Deese (b) (4)	12 Apr 2021 18:32:02
DataPoint inactivated with code reason code Data not required.	Teresa Deese (b) (4)	12 Apr 2021 18:05:51
User entered '0'	System	05 Apr 2021 21:19:33

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:42:37

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:09:50
User closed query 'please confirm with subject any con meds for pain after surgeries' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:09:37
Query 'please confirm with subject any con meds for pain after surgeries' answered with 'confirmed--subject reported none verbally at visits and email from subject now filed in source for confirmation/verification of site-reported information' (Site from CRA).	Erica Osmundsen (b) (4)	08 Apr 2021 18:32:32
User opened query 'please confirm with subject any con meds for pain after surgeries' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:05:56
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:51:57

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 14:43:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 14:43:47
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	19 Sep 2020 02:04:49 19 Sep 2020 02:04:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:53:36
Data point term sent to Coder User entered 'Allopurinol'	System Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:53:16 24 Aug 2020 13:52:56

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of GOUT. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:52:50
Query 'Per DM CLR: Please update the indication to reflect the location and type of GOUT. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:04:10
User entered 'GOUTY ARTHRITIS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:04:00
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of GOUT. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:00:23
User entered 'Gout'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 13:52:56

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '300'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2005'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:03:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:03:02
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	24 Aug 2020 14:03:02
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 13:52:56
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 13:52:56
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:52:56

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:52:56

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 13:52:56

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TERAZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 02:12:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 02:12:36
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	19 Sep 2020 02:11:57 19 Sep 2020 02:11:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TERAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:05:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:05:33
Data point term sent to Coder User entered 'Terazosin'	System Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:02:47 24 Aug 2020 14:02:29

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:53:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:11:33
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:11:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 08:42:57
User entered 'Prostate'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:02:29

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '2'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2011'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:02:29
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:02:29

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:02:29

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:02:29

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 14:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 14:05:43
Data point term sent to Coder	System	24 Aug 2020 14:04:53
User entered 'Levothyroxine'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:04:18

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Hypothyroidism'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '88'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:53:32
Query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:08:21
User entered 'ug (ug)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:08:12
User opened query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:01:38
User entered 'Other (OTHER)'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:04:18

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:08:12
User entered 'MCG'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2011'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:04:18
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:04:18

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:04:18

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:04:18

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
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: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 15:40:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:40:37
Data point term sent to Coder	System	24 Aug 2020 14:08:01
User entered 'Pantoprazole NA'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:07:49

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Acid Reflux'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '40'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2000'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:07:49
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:07:49

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:07:49

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:07:49

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 02:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 02:06:45
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4)	19 Sep 2020 02:05:50 19 Sep 2020 02:05:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:57:42
Data point term sent to Coder User entered 'Lisinopril'	System Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:10:08 24 Aug 2020 14:09:52

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:53:51
Query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:05:35
User entered 'HYPERTENSION' reason for change:	Erica Osmundsen (b) (4)	19 Sep 2020 02:05:29
Data Entry Error		
User entered 'HYPERTENSIPN' reason for change:	Erica Osmundsen (b) (4)	19 Sep 2020 02:05:23
Data Entry Error		
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:01:15
User entered 'Heart Disease'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '20'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:09:52
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:09:52

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:09:52

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:09:52

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 02:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 02:07:45
Data point term sent to Coder Coding entries removed.	System Erica Osmundsen (b) (4) (b) (4) (b) (4)	19 Sep 2020 02:06:51 19 Sep 2020 02:05:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:40:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:40:38
Data point term sent to Coder User entered 'Carvedilol'	System Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:11:11 24 Aug 2020 14:10:43

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:54:00
Query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 02:05:59
User entered 'HYPERTENSION' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Sep 2020 02:05:51
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of HEART DISEASE. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:00:57
User entered 'Heart Disease'	Tiffany Jewell (b) (4) (b) (4)	24 Aug 2020 14:10:43

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '50'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	24 Aug 2020 14:10:43
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:10:43

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 14:10:43

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 14:10:43

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 20:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 20:45:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 20:30:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 20:30:51
Data point term sent to Coder Coding entries removed.	System Teresa Deese (b) (4)	02 Mar 2021 20:14:20 02 Mar 2021 20:14:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: ALIROCUMAB, PRODUCTSYNONYM: PRALUENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Feb 2021 16:07:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Feb 2021 16:07:08
Data point term sent to Coder User entered 'Praluent'	System zackery harmon (b) (4) (b) (4)	21 Feb 2021 16:05:45 21 Feb 2021 16:05:04

PRODUCTION RELEASE (v12.003
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US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Hyperlipidemia'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '75'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'mg (mg)'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'other (OTHER)'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'EVERY 2 WEEKS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	11 Mar 2021 21:37:52
User entered '2 times a month'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
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)	03 Mar 2021 09:37:45
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	02 Mar 2021 20:14:16
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 20:14:10
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)	26 Feb 2021 14:49:59
User entered 'Oral (ORAL)'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 16:05:04

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '08 Feb 2021'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered '0'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered empty.	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
	(b) (4)	
User entered 'No (N)'	zackery harmon (b) (4)	21 Feb 2021 16:05:04
	(b) (4)	

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 16:05:04

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 16:05:04

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Feb 2021 16:05:04

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:21:46
Data point term sent to Coder	System	05 Apr 2021 21:14:07
User entered 'HEPARIN'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:52
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:53
User entered 'RIGHT CAROTID ENDARTERECTOMY PROCEDURAL PROPHYLAXIS'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:55
User entered '5000'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:57
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:59
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:01
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:03
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:04
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:07
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:08
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:10
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:12
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:15
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:16
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User entered empty.	System	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User entered empty.	System	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:02:56
User entered empty.	System	05 Apr 2021 21:13:34

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:20:56
Data point term sent to Coder	System	05 Apr 2021 21:15:14
User entered 'GENERAL ENDOTRACHEAL ANESTHESIA'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:29
User entered 'RIGHT CAROTID STENOSIS'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:30
User entered 'UNK'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:32
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:33
User entered 'UNKNOWN'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:35
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:38
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:40
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:43
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:44
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:46
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:48
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:50
User entered '21 Oct 2020'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:52
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User entered empty.	System	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User entered empty.	System	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:01
User entered empty.	System	05 Apr 2021 21:14:47

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:21:46
Data point term sent to Coder	System	05 Apr 2021 21:17:17
User entered 'HEPARIN'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:01
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:03
User entered 'LEFT CAROTID ENDARTERECTOMY PROCEDURAL PROPHYLAXIS'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:06
User entered '4000'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:07
User entered 'IU (IU)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:09
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:11
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:13
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:15
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:16
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:20
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:23
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:27
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User entered empty.	System	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User entered empty.	System	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:06
User entered empty.	System	05 Apr 2021 21:17:01

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 06:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:31:42
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:43:39
Data point term sent to Coder	System	05 Apr 2021 21:18:18
User entered 'GENERAL ENDOTRACHEAL ANESTHESIA'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:41
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:43
User entered 'LEFT CAROTID STENOSIS (PROCEDURAL ANESTHESIA FOR LEFT CAROTID ENDARTERECTOMY)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:46
User entered 'UNK'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:47
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:49
User entered 'UNKNOWN'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:51
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:53
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:55
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:57
User entered empty.	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:43:59
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:44:01
User entered '0'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:44:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:44:05
User entered '19 Jan 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:44:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User entered empty.	System	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User entered empty.	System	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:42:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:03:14
User entered empty.	System	05 Apr 2021 21:18:10

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:42:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Feb 2021 16:35:01
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	13 Oct 2020 18:50:49

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered '21 Oct 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:15:32
User entered '20 Nov 2020'	Teresa Deese (b) (4)	12 Feb 2021 16:35:32

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered 'RIGHT CAROTID ENDARTARECTOMY WITH BOVINE PATCH ANGIOPLASTY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:15:32
User entered 'right carotid endartarectomy'	Teresa Deese (b) (4)	12 Feb 2021 16:35:32

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered 'Medical History (MH)' reason for change: Data Entry Error	Teresa Deese (b) (4)	06 Apr 2021 12:37:04
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:21:15
User entered 'Medical History (MH)'	Teresa Deese (b) (4)	12 Feb 2021 16:35:32

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:42:37

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered empty.	Teresa Deese (b) (4)	12 Feb 2021 16:35:32

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:42:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:57:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered '19 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:15:54
User entered '20 Jan 2021'	Erica Osmundsen (b) (4)	11 Mar 2021 21:51:07

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:42:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:57:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered 'LEFT CAROTID ENDARTERECTOMY WITH BOVINE PATCH ANGIOPLASTY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:15:54
User entered 'LEFT CAROTID endarterectomy'	Erica Osmundsen (b) (4)	11 Mar 2021 21:51:07

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:42:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:57:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered 'Medical History (MH)' reason for change: Data Entry Error	Teresa Deese (b) (4)	06 Apr 2021 12:37:11
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 21:21:25
User entered 'Medical History (MH)'	Erica Osmundsen (b) (4)	11 Mar 2021 21:51:07

US3202197

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:42:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:57:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:41:16
User entered empty.	Erica Osmundsen (b) (4)	11 Mar 2021 21:51:07

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'USA-US128-2021-MRNA-1273-P301000015'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Mark'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'McKenzie'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered 'US'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 13:18:17
User entered '2'	System	13 Apr 2021 18:29:36
User entered '1'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'USA-US128-2021-MRNA-1273-P301000015'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Mark'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'McKenzie'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered 'US'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 13:18:17
User entered '2'	System	13 Apr 2021 18:29:36
User entered '1'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered '06/Apr/2021 13:10'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'USA-US128-2021-MRNA-1273-P301000015'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Mark'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'McKenzie'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered 'US'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 13:18:17
User entered '2'	System	13 Apr 2021 18:29:36
User entered '1'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:14
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
User entered '13/Apr/2021 11:29'	(b) (4) System	13 Apr 2021 18:29:36

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:14
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:29:36

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'USA-US128-2021-MRNA-1273-P301000015'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Yes (Y)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'No (N)'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'Mark'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:10:38
User entered 'McKenzie'	System	06 Apr 2021 18:10:23

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 13:18:03
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:02:45
User entered 'US'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Apr 2021 13:18:17
User entered '2'	System	13 Apr 2021 18:29:36
User entered '1'	System	06 Apr 2021 18:10:45

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:42:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:44
User entered '16/Apr/2021 06:18'	(b) (4) System	16 Apr 2021 13:18:17

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:42:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:18:17

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'USA-US128-2021-MRNA-1273-P301000017'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Mark'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'McKenzie'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
User entered 'US'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 14:23:11
User entered '1'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'USA-US128-2021-MRNA-1273-P301000017'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Mark'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'McKenzie'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
User entered 'US'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 14:23:11
User entered '1'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
User entered '06/Apr/2021 12:32'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:42:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 19:32:40
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 19:32:25

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'USA-US128-2021-MRNA-1273-P301000017'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Yes (Y)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'No (N)'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'Mark'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 19:32:15
User entered 'McKenzie'	System	06 Apr 2021 19:30:22

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:36:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:04:24
User entered 'US'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:42:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 14:23:11
User entered '1'	System	06 Apr 2021 19:32:40

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:27
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:27
User entered '13/Apr/2021 07:23'	(b) (4) System	13 Apr 2021 14:23:11

US3202197

Folder: SAE USA-US128-2021-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:42:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:08:27
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:34:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:23:11